IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF SAN DIEGO

Coordination Proceeding Special Title (Rule 1550(b)). In re TOBACCO CASES II This Document Relates to: The People of the State of California, and American Environmental Safety Institute v. Philip Morris Incorporated, et al., Los Angeles Superior Court, Case No. BC 194217 The People of the State of California, City of San Jose, and Paul Dowhall v. Brown & Williamson Corp., et al., San Francisco Superior Court, Case No. 996781 SERVICE LIST "B"	JCCP No. 4042 DEPOSITION OF MELBOURNE HOVELL Ph.D. VOLUME I (Pages 1 - 192)

TAKEN ON: Monday, July 31, 2000

TAKEN AT: 550 West C Street, Suite 1440
San Diego, California

REPORTED BY: Jeannette K. Jessup
CSR No. 8573, RPR

APPEARANCES:

FOR PLAINTIFFS IN THE PEOPLE OF CALIFORNIA/AESI:

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BY: NEIL D. KODSI, ESQ. (P.M. ONLY)

ALSO PRESENT: Robert Jordan, AJL Videotaping

I N D E X

E X H I B I T S

C E R T I F I C A T E

I, the undersigned, do hereby certify that I have read the foregoing deposition and that, to the best of my knowledge, said deposition is true and accurate (with the exception of the following changes listed below):

Page	Line	Explanation

_____

MELBOURNE HOVELL, Ph.D.

SAN DIEGO, CALIFORNIA; MONDAY, JULY 31, 2000
9:05 A.M.

THE VIDEOGRAPHER: This is the videotape deposition of Melbourne Hovell, Ph.D., MPH, taken by the defendants in the matter of the People of the State of California, City of San Jose, in re: Tobacco Cases II, in the Superior Court of California, County of San Diego, Case Number JCCP 4042, held in the offices of Vail, Christians & Associates, 550 West C Street, Suite 1440, San Diego, 09:06:04 09:06:14 09:06:19 09:06:22 09:06:26 09:06:30 09:06:34 09:06:39

California, 92101. Today's July 31st, 2000. The time is now 9:06 a.m. 09:06:45 09:06:51

My name is Robert Jordan. I'm from the firm of AJL Videotaping Services in San Diego, and I'm the videotape operator. The certified shorthand reporter is Jeannette Jessup with Vail, Christians in San Diego. 09:06:54 09:06:57 09:06:59 09:07:04 09:07:07

For the video record, counsel may now introduce themselves. 09:07:08 09:07:10

MR. CAFFERTY: Morning, Dr. Hovell. My name is Patrick Cafferty. I represent Philip Morris. 09:07:12 09:07:14

THE WITNESS: Good morning.

MR. LENDRUM: Good morning. Jeffrey Lendrum on behalf of Liggett Group. 09:07:17 09:07:19

MR. HOLTMANN: John Holtmann for Philip Morris. 09:07:21

MS. FROSTROM: And Karen Frostrom for the plaintiff. 09:07:23 09:07:24

THE WITNESS: And I'm Mel Hovell. 09:07:26

THE VIDEOGRAPHER: And the doctor may now be sworn.

MELBOURNE HOVELL, Ph.D.
being first duly sworn, testified as follows:

EXAMINATION BY MR. CAFFERTY:

Q. Dr. Hovell, good morning. Could you please first tell me what you understand this case to be about. 09:07:39 09:07:44 09:07:47

A. I understand it to be about the possible health effects of passive smoke exposure. 09:07:47 09:07:48

Q. What do you understand your role to be in this case? 09:07:53 09:07:54

A. My role is to look at some of the research methods, also sometimes known as epidemiological procedures, that serve as the foundation for the EPA -- Cal EPA report and related literature. 09:07:55 09:07:59 09:08:02 09:08:07

Q. Are there any particular health end points that you understand your role to be to address in this case? 09:08:13 09:08:15 09:08:18

A. I was asked to take a special look at those relationships that might pertain to vascular and heart disease. Otherwise, I was looking at any form of ill health outcomes. 09:08:19 09:08:22 09:08:26 09:08:32

Q. We'll come back to that later, because I want to understand fully what it is that you've done. 09:08:38 09:08:40

Have you ever had your deposition taken before? 09:08:43 09:08:44

A. Yes. 09:08:45

Q. How many times? 09:08:45

A. Once. 09:08:46

Q. Okay.

A. That is in one case. 09:08:47

Q. In one case, okay. And what -- what kind of case was that? 09:08:49 09:08:52

A. A swimming pool suit. 09:08:53

Q. All right. And were you a party to that lawsuit? 09:08:54 09:08:56

A. Yes, I was. 09:08:57

Q. Okay. Were you the plaintiff or the defendant? 09:08:58 09:08:59

A. I was the plaintiff. 09:09:00
Q. All right. And what was the case about? 09:09:02
A. Failed pool construction. 09:09:03
Q. Okay. How long ago did you have your deposition taken in that case? 09:09:07 09:09:09
A. Five years maybe. I'm not sure. 09:09:15
Q. Was that case in state court or in federal court? 09:09:18 09:09:22
A. I think it was in state court. 09:09:22
Q. Was it here in San Diego -- 09:09:23
A. Yes, it was.
Q. -- or was it elsewhere? 09:09:25

A. It was here in San Diego. 09:09:26
Q. Okay. Let's -- let's review a couple of general instructions, since you don't have extensive experience with the deposition process. And I'm sure Ms. Frostrom has probably reviewed some of these with you, but it always helps to go through them again. 09:09:27 09:09:29 09:09:32 09:09:34 09:09:38
First, you understand that you're under oath, and that you have the same obligation to tell the truth in this informal setting as you would if we were in the formal setting of a courtroom. Do you understand that? 09:09:41 09:09:42 09:09:45 09:09:48 09:09:50
A. Yes. 09:09:50
Q. Okay. Do you also understand that I will be asking you questions today, you will be giving answers, other counsel may have things to say on the record, but that at the end of this deposition the court reporter will prepare a transcript, and that you will then have an opportunity to review the transcript after it's prepared. Do you understand that? 09:09:51 09:09:54 09:09:56 09:09:58 09:10:00 09:10:04 09:10:06 09:10:09
A. Yes. 09:10:09
Q. Do you also understand that you have the right to make changes to the transcript after it's prepared, but that we have the right to make any -- to make comments about any changes that you might make? 09:10:09 09:10:11 09:10:14 09:10:17 09:10:20
A. Yes. 09:10:20
Q. It's also important, since the reporter is trying to take down what everyone says here today, that you and I don't speak at the same time. And I'll agree to try not to speak at the same time if you'll agree not to try -- to try not to speak at the same time as me. Is that a deal? 09:10:21

09:10:24 09:10:28 09:10:31 09:10:34 09:10:37
A. Okay. 09:10:39
Q. Okay. Thank you. It's also important, because the reporter is taking down your testimony today as well as everything that's said here, that you give audible answers. So if you would try to always give an audible answer, not just a nod of the head or an "uh-huh," that will make it much easier for the court reporter. So please try to remember that. 09:10:40 09:10:42 09:10:44 09:10:47 09:10:51 09:10:54 09:10:57 09:10:59
A. I'll do my best. 09:11:00
Q. Thank you. Also, we're here today to try to get your accurate testimony. We don't want you to guess or speculate. And, in particular, we want to make sure that you understand all of the questions that we ask. This is a complex subject, as you well know, having been involved in it for many years, so 09:11:01 09:11:04 09:11:08 09:11:12 09:11:13 09:11:17

that if there are any questions that are asked that you don't understand, please ask me to clarify them, or anyone else who asks the questions, and we'll be happy to do so. Do you understand that? 09:11:21 09:11:23 09:11:26 09:11:34

A. Yes -- 09:11:34

Q. Do you think you can do that?

A. -- I do. 09:11:34

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Q. All right. Also, these depositions tend to go on for a while. So it's important that if at any time you want to take a break, just let us know and we would be happy to take a break. Okay? 09:11:34 09:11:37 09:11:39 09:11:43

A. Yes. 09:11:45

Q. Finally, are you taking any medication or any other substances that would impair your ability to testify accurately today? 09:11:45 09:11:47 09:11:50

A. No. 09:11:51

Q. What do you understand environmental tobacco smoke to be? 09:11:57 09:12:01

A. Environmental tobacco smoke is generally considered to be the smoke that emanates from a cigarette, as also known as sidestream smoke, as it burns, say, in an ashtray. It's also that smoke that occurs when a smoker exhales, and then those combinations are breathed by another party. 09:12:03 09:12:06 09:12:08 09:12:11 09:12:15 09:12:20

Q. Do you consider yourself to be an expert in environmental tobacco smoke? 09:12:22 09:12:25

A. I can't answer that easily with a "yes" or "no." I consider myself to understand issues of changing behavior that may affect exposure, and I understand some of the research methods involved in tobacco smoke. I am not a toxicologist. 09:12:28 09:12:31 09:12:33 09:12:37 09:12:40

Q. Are you an expert in ETS chemistry? 09:12:42

A. No. 09:12:46

Q. And, by the way, when we talk about environmental tobacco smoke today, if I use the term 09:12:46 09:12:47

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"ETS," can we agree that that means environmental tobacco smoke? 09:12:49 09:12:52

A. Absolutely. 09:12:53

Q. Is that the terminology that you typically use? 09:12:53 09:12:56

A. That is the terminology I would use. 09:12:56

Q. Thank you. When you say that you understand some of the research methods involved in tobacco smoke, what were you referring to? 09:12:59 09:13:05 09:13:07

A. Well, one of my specialties is epidemiology, and from behavioral psychology I'm an experimental psychologist and developmental psychologist. That combination of training enables me to examine the research design of many different kinds of studies, from animal studies through people studies. 09:13:11 09:13:13 09:13:19 09:13:22 09:13:24 09:13:28 09:13:32

What I can't do in that context is serve as an advanced expert in the more advanced statistics. And what I can't do is talk to the physiology, pathophysiology or chemistry in certain specialty studies that may be dependant on that. But the basic structure of the design I can still review. 09:13:34 09:13:36 09:13:40 09:13:43 09:13:47 09:13:51

Q. What is an experimental psychologist? 09:13:53

A. An experimental psychologist is one that specializes in experiments of people for different purposes. It could be for learning. It could be for 09:13:57 09:13:59 09:14:02

different kinds of behavior change. It's one of the many specialists within the field of psychology. 09:14:05 09:14:08

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Q. And what is a developmental psychologist? 09:14:11
A. Developmental psychologists specialize in human development, frequently child development, but it now extends from birth through senior citizen. 09:14:13 09:14:15 09:14:18
Q. Now, I believe you mentioned that you consider yourself to be an expert in changing behavior that may affect ETS exposure? 09:14:23 09:14:24 09:14:27
A. That's correct. 09:14:30
Q. What did you mean by that? 09:14:30
A. Much of the research that we've done has been focused on looking at how families, where a child is exposed, can alter their smoking patterns in a way to protect children from exposure. 09:14:33 09:14:36 09:14:39 09:14:42
Q. We'll talk a little bit more about that later. 09:14:48 09:14:49
Have you ever been designated as an expert witness in any other case? 09:14:51 09:14:54
A. One other case many years ago. 09:14:57
Q. What was that case? 09:15:00
A. It was a case regarding special education for a child in San Francisco. Actually the child was in Hayward. The case was in San Francisco. 09:15:02 09:15:05 09:15:08
Q. How many years ago was that? 09:15:12
A. Many. It would have been about 197 -- maybe '78 to '80. 09:15:14 09:15:17
Q. Did you give testimony -- 09:15:19
A. No. 09:15:21
Q. -- in court in that case? 09:15:21

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A. No, I did not. 09:15:23
Q. And you didn't give a deposition either? 09:15:23
A. No. I gave a formal report, a written report of assessment, but I did not give any formal depositions. 09:15:25 09:15:29 09:15:33
Q. Who retained you in that case -- 09:15:33
A. The --
Q. -- as an expert? 09:15:35
A. The plaintiff. 09:15:35
Q. Okay. What was the nature of the report that you gave? 09:15:37 09:15:38
A. The nature of the report was an assessment of the teaching procedures used to address the special education needs of the particular child, and it was based on direct observations of teaching procedures in the child's school. 09:15:39 09:15:42 09:15:45 09:15:47 09:15:50
Q. Okay. What conclusions did you reach? 09:15:53
A. We reached the conclusion that the special education procedures being provided for the child were not satisfactory, either for that child or for the others in the same special education class. 09:15:57 09:15:59 09:16:01 09:16:05
Q. Was that report filed with the court? 09:16:10
A. It was filed with the attorney. I don't know whether it was filed with the court. 09:16:12 09:16:13
Q. Have you ever been qualified as an expert witness in any case? 09:16:16 09:16:20
A. No. 09:16:23
Q. Have you ever given trial testimony in any case? 09:16:25

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09:16:29
A. No. 09:16:29

Q. In your swimming pool case, you didn't testify at trial? 09:16:30 09:16:33
A. No. We did not go to trial. 09:16:34
Q. Was that case settled? 09:16:35
A. It was. 09:16:36
Q. Have you ever given any testimony before congress? 09:16:37 09:16:39
A. No. 09:16:40
Q. Have you ever given any testimony before the state legislature? 09:16:41 09:16:43
A. No. 09:16:45
Q. Have you ever testified before any state agency? 09:16:45 09:16:47
A. Testified in a formal sense, no. I've had -- I have had roles with state agencies that involves my expert background, but not as formal testimony. 09:16:58 09:16:58 09:16:58
Q. Okay. All right. Have you ever given any testimony before a federal agency? 09:17:01 09:17:01
A. No. 09:17:05
Q. Could you please tell me what involvement you have had with state agencies that involves your expertise. 09:17:06 09:17:09 09:17:12
A. Yes. I have been involved in a number of public health functions. Those range from participating in the Tobacco-Related Disease Research Program activities, some of which have involved 09:17:13 09:17:17 09:17:22 09:17:25

funding decisions, where I've either been a reviewer for grants or -- not a reviewer for grants, but a reviewer on abstracts, or I have been a recipient of grants. Some of it has involved the office of AIDS within the state health department. And assisting with policy and planning meetings, as well as a recipient of research and evaluation funds. 09:17:29 09:17:31 09:17:34 09:17:38 09:17:41 09:17:44 09:17:47
Q. Is there anything else that you've done with state agencies as an expert? 09:17:55 09:17:57
A. There have been many such meetings over the course of, you know, the last 20 years, so there are many of those like that. But, in general, that would cover it. 09:18:01 09:18:04 09:18:06 09:18:09
Q. Okay. When did you first become involved with the Tobacco-Related Disease Program? 09:18:09 09:18:11
A. Gosh, I'm not sure of the exact date, but it would have been early in the existence of the program. So the first few years, we submitted proposals to them early on, and at least two were funded early on. I don't remember the exact dates now. Those could be obtained later. 09:18:16 09:18:18 09:18:20 09:18:25 09:18:28 09:18:32
Q. Okay. Approximately how long ago was that? 09:18:34
A. Early '90s, at the very least. '92, '94, somewhere in there. 09:18:41 09:18:46
Q. Okay. And what were the two proposals that were funded by the Tobacco-Related Disease Program? 09:18:48 09:18:50
A. One was a study that was looking at the degree to which clinicians could prevent tobacco 09:18:54 09:18:56

initiation in adolescence and preadolescence. So it was a tobacco prevention study. And it was funded by the TRDRP. And that study has been published in the American Journal of Public Health. 09:19:00 09:19:03 09:19:07 09:19:12
The second one was a passive smoke study with asthmatic children. And in that study we worked with families to see if they could reduce the 09:19:16 09:19:19 09:19:23

exposure the children might have from one of the smoking parents. And that study was published in CHEST. 09:19:26 09:19:28 09:19:33

Q. Which study did you do first, the tobacco prevention or the passive smoke study? 09:19:38 09:19:44

A. They were overlapping in time. I can't remember which one was funded first. I could find that information out, if you'd like. 09:19:46 09:19:48 09:19:51

Q. Okay. I think maybe, when we go through your resume, we'll be able to -- 09:19:52 09:19:54

A. Yes. 09:19:56

Q. -- pick some of that out. 09:19:57

A. Yes. The funded grants are listed there, and they're dated. 09:19:57 09:20:02

Q. Okay. Are those the only two studies that you have had funded by the Tobacco-Related Disease Program? 09:20:04 09:20:06 09:20:10

And, by the way, you used the term before TRDRP, I believe? 09:20:10 09:20:12

A. Yes. 09:20:16

Q. What does that stand for? 09:20:16

A. The Tobacco Related -- Tobacco-Related Disease Research Program, I believe. 09:20:17 09:20:18

Q. Okay. So if you use TRDRP, that's what you mean? 09:20:21 09:20:25

A. That's what I mean. 09:20:25

Q. Okay. Are those the only two studies that you've had funded by the Tobacco-Related Disease Research Program? 09:20:26 09:20:28 09:20:32

A. I have been involved in other studies that have been funded by it, not necessarily directly to me. The most recent one is a study of tobacco use in Koreans. And it was just recently funded to a colleague of mine, Dr. Hofstetter. And I will be involved in that as a co-investigator. And that study is centered in the research center that I direct. 09:20:33 09:20:34 09:20:38 09:20:41 09:20:45 09:20:49 09:20:51 09:20:54

Q. What's the name of that research center? 09:20:58

A. The Center for Behavioral Epidemiology and Community Health. 09:20:59 09:21:05

Q. What is behavioral epidemiology? Oh, thank you. 09:21:06

A. Behavioral epidemiology, the way we define it is that it is the research procedures employed to understand the causes of behavior. It also includes exploring the relationships between behavior and ill health. So at one level we are looking for what things might precede and, in some sense, cause behavior. At the next level we're looking at how 09:21:12 09:21:17 09:21:20 09:21:26 09:21:28 09:21:32 09:21:35

behavior might have some influence on health outcomes. 09:21:39 09:21:41

Q. And what is the study that Dr. Hofstetter's going to be performing regarding tobacco smoke in Koreans? 09:21:57 09:22:01 09:22:04

A. We'll be doing a cross-sectional survey of Koreans to determine the degree to which they smoke, the degree to which their family members may be exposed to ETS, and some of the correlates that might explain both the smoking practices and the passive smoking exposure practices. 09:22:05 09:22:09 09:22:11 09:22:14 09:22:19 09:22:22

Q. One of the things that's important in 09:22:25

giving your testimony, because this is a complicated area, is to try to keep it in simple terms. So when you use technical terms, what I'll try to do is follow up and -- 09:22:27 09:22:30 09:22:34 09:22:37

A. That's fine.

Q. -- see if we can understand them. 09:22:37

What did you mean by a correlate? And that's c-o-r-r-e-l-a-t-e? 09:22:38

A. Correct. 09:22:47

Q. All right. What did you mean by correlate? 09:22:47

A. In this case it means another event that's associated with either smoking or passive smoke exposure. 09:22:47 09:22:49 09:22:52

Q. So, for example, in this tobacco smoke in Korean study that Dr. Hofstetter is going to be performing, what are the correlates that would be considered? 09:22:52 09:22:56 09:22:58 09:23:01

A. There are many. One might be, for example, social class, education level of the family members, immigrant status, or length of time in the U.S. Those -- those kinds of conditions might predict changes -- or levels of smoking, or differences in smoking patterns. Other correlates might involve the degree to which there are social support systems for smoking behavior, others in the immediate peer network or family network who also smoke, may cluster. Those would be viewed as possible influences on the practices of smoking, and on the practices of exposing children to passive smoke. 09:23:02 09:23:06 09:23:11 09:23:14 09:23:17 09:23:22 09:23:27 09:23:30 09:23:33 09:23:38 09:23:40 09:23:43

Q. Would this study then be considered a behavioral epidemiology study? 09:23:46 09:23:48

A. Yes. 09:23:51

Q. When is the study anticipated to be completed? 09:23:51 09:23:53

A. In approximately three years. 09:23:54

Q. How much funding was provided for the study? 09:23:56 09:23:58

A. I think it was about $600,000. I don't have the exact figure. 09:24:00 09:24:04

Q. How much study was provided for your -- strike that. 09:24:06

How much funding was provided for your earlier passive smoke study? 09:24:08 09:24:11

A. Approximately the same amount, if I recall. It might have been a little less. 09:24:13 09:24:15

Q. How much was provided for your study of tobacco smoking prevention? 09:24:18 09:24:23

A. That one was about -- if I recall correctly, about 1.5 million. 09:24:28 09:24:30

Q. For all three of those studies, has all of the money for those studies come from the Tobacco-Related Disease Research Program? 09:24:33 09:24:36 09:24:39

A. The figures I've given you is all of the money that has come from the TRDRP. There may -- there are generally other resources I have available in the center that sometimes get used to supplement those funds. So there may be additional funding that's discretionary that I have from the university. 09:24:41 09:24:44 09:24:48 09:24:50 09:24:53 09:24:57

Q. And -- 09:25:00

A. I don't know. It would be a small amount, and it would be incidental. 09:25:00 09:25:02

Q. About how much is your annual budget for this discretionary funding? 09:25:04 09:25:06
A. Probably in the neighborhood of $100,000. 09:25:10
Q. Okay. Are there any other studies that your Center for Behavioral Epidemiology and Community Health have performed, or are in the process of performing, that have been, or are being, funded by the Tobacco-Related Disease Research Program? 09:25:18 09:25:20 09:25:24 09:25:26 09:25:29
A. I don't think so. I can check that again, or when we go over the resume, the C.V., I would be able to confirm that. But I believe my funding for related stuff is all from other sources at this time. 09:25:40 09:25:42 09:25:46 09:25:48

Q. Okay. Is it your opinion that smoking should be banned in California? 09:25:51 09:25:54
A. Yes. 09:25:57
Q. Is it also your opinion that smoking should be banned in the United States? 09:25:59 09:26:01
A. Yes. 09:26:02
Q. Is it also your opinion that smoking should be banned world-wide? 09:26:03 09:26:05
A. Yes. 09:26:07
Q. Has -- would it be fair to say that much of your professional work is now devoted towards working towards a ban of smoking in the United States? 09:26:10 09:26:12 09:26:17
A. Absolutely not. 09:26:20
MS. FROSTROM: Objection; assumes facts, argumentative. 09:26:22 09:26:23
BY MR. CAFFERTY: 09:26:24
Q. About how much of your professional work currently is devoted towards seeking a scientific basis for banning smoking in the United States? 09:26:25 09:26:29 09:26:33
A. None of it. 09:26:36
Q. Okay. Have you ever been involved in any other matters with the plaintiff's attorneys in this case? 09:26:37 09:26:47 09:26:49
A. No. 09:26:50
Q. Have you ever been involved in any other tobacco cases? 09:26:51 09:26:53
A. No. 09:26:55

Q. Have you ever worked as a -- an expert consultant, not designated as an expert witness in litigation? 09:26:58 09:27:03 09:27:06
A. No. 09:27:07
MR. CAFFERTY: Let's mark a couple of documents here. I've got it. Do you have a copy of that? 09:27:12 09:27:14 09:27:35
(Exhibits 564 and 565 were marked for identification.)
BY MR. CAFFERTY:
Q. Dr. Hovell, I'm showing you two documents that have been marked for purposes of identification as Exhibit 564 and 565. 09:27:45 09:27:49 09:27:53
A. Uh-huh.
Q. Do you have those in front of you? 09:27:57
A. Yes. 09:27:58
Q. And that little yellow Post-it sticker is the -- 09:28:00 09:28:02
A. Designation. 09:28:03
Q. -- the designation. 09:28:03
Now, one of these, Exhibit 564, is a group of documents that Ms. Frostrom provided to me last 09:28:04 09:28:07

week. 09:28:11
A. Uh-huh.
Q. And the second, 565, is a group of 09:28:12
documents that Ms. Frostrom provided to me this 09:28:15
morning. 09:28:18
A. Uh-huh. 09:28:19

THE VIDEOGRAPHER: Excuse me, Doctor. 09:28:20
You're going to have to raise your mike because 09:28:21
you're covering it with your -- 09:28:24
THE WITNESS: Pardon me. 09:28:27
THE VIDEOGRAPHER. That's okay. It makes a
lot of difference. 09:28:31
BY MR. CAFFERTY: 09:28:31
Q. Is 565 a group of documents that you 09:28:31
brought with you today? 09:28:35
A. Yes, it is. 09:28:36
Q. All right. Now, let's turn to kind of the 09:28:37
middle of that document. There's a document entitled 09:28:39
"Defendants' Notice of Taking Deposition Duces Tecum 09:28:45
of Melbourne" -- "Melbourne F. Hovell, Ph.D.," and 09:28:48
it's PX-MF -- MFH-000105. Do you have that in front 09:28:51
of you? 09:28:58
A. I do. 09:28:58
Q. Okay. Now, this is a -- a notice of your 09:28:59
-- your deposition that was going to -- that is 09:29:00
occurring today. Have you seen that document before? 09:29:07
A. Yes, I have. 09:29:07
Q. Okay. And is that a document that's in 09:29:07
your files regarding this case? 09:29:07
A. Yes, it is. 09:29:10
Q. Okay. Now, one of the things that this 09:29:11
deposition notice asks is for you to produce certain 09:29:13
documents in connection with this deposition. Is the 09:29:17
combination of Exhibit 564 and 565 all of the 09:29:23

documents that you have in your file regarding this 09:29:30
case? 09:29:32
A. I'm not sure. Just a moment. Let's see. 09:29:35
Q. And I'll -- I'll represent to you that I 09:29:43
have copied, I believe, everything that Ms. Frostrom 09:29:45
gave me. And a number of the things that she gave me 09:29:49
are front pages of studies, rather than the entire 09:29:51
studies. 09:29:54
A. Okay. I have a large number of studies, 09:29:55
and I did not bring them all with me here. This is 09:29:57
at least a strong representation from them. It may 09:30:00
be all of them. And this is all that I had from this 09:30:05
morning. 09:30:06
Q. Okay. And when you say this is all that 09:30:08
you had, it's Exhibit 565 -- 09:30:11
A. 565.
Q. -- is all that you brought with you today? 09:30:13
A. Yes.
Q. Okay.
A. And these are duplicates here. What 09:30:15
happens here is parts of this. 09:30:18
Q. All right. Now, when you say "these are 09:30:21
duplicates," what are you referring to? 09:30:22
A. These studies that I have brought here are 09:30:24
duplicates of some of these that are in the back 09:30:26
here. 09:30:29
Q. All right. And so those are other 09:30:29

documents that you brought with you this morning, but we haven't marked them as exhibits, correct?

A. I believe they are marked in this. That's -- that's what I believe is all here. Without going through them one at a time, I can't -- I can't be sure. But I brought -- these were available last week for this purpose. And I think they were marked.

Q. Okay. And then the -- the handwritten notes -- I'm sorry, if we could move that. The -- the handwritten notes on that kind of grayish sheet --

A. Uh-huh.

Q. -- underneath there, is that a copy of what you provided?

A. Yes, this is a copy.

Q. The original of --

A. The original.

Q. -- the copy?

A. Correct.

Q. All right. We have got to try to talk one at a time. I know it's hard to do because I have trouble myself, but we'll do our best.

A. Okay.

Q. Okay. So just so the record is clear, the documents that appear as 565, you have the originals in front of you?

A. That's right.

Q. All right. Could you just summarize briefly for me what is included in Exhibit 565.

A. These are my notes regarding some of the articles that I have read, and regarding the description of the deposition to be taken today, as well as a document that I just recently received on Friday from the plaintiff's attorneys regarding a list of possible references to be considered by me. I have not had time to look at that yet.

Q. All right. And which page was that?

A. That is -- well, it's the memo that's dated July 28, 2000 to me from client, Tobacco II, and from Karen Frostrom. And following that, on what's noted here is 5203 in pencil, at the bottom is a series of references. And that reference list goes forward for a number of pages.

Q. What's your understanding as to what the source of that reference list is?

A. I'm not sure. I believe this came from another deposition. But I don't -- I have not discussed the details of that. And I have not had time to read through this list yet.

Q. Has Ms. Frostrom or anyone from your firm given you any instructions about what documents you were to provide to them for them to provide to us?

A. Yes.

Q. What did they tell you?

A. They told me to give you -- or to give them the materials that I was reading. And I have done that as of last Tuesday, I believe, a week ago.

And I'm still looking through materials, and I'm still -- I have actually done some literature reviews. And I have not yet obtained all of that

literature from the library. Some of it is on library loan. It may or may not show up. 09:33:13 09:33:18

Q. Let's come back to that because I want to know what it is that you've done and what it is that you still have to do. And it sounds like you still have more that you have to do. And we'll explore that later. 09:33:21 09:33:24 09:33:26 09:33:29 09:33:30

A. Okay. 09:33:31

Q. Have you brought any other documents with you today, other than ones that are in 564 and 565? 09:33:40 09:33:42

A. This is the original of that list that I had. I have some business cards from other associates and a tablet. 09:33:48 09:33:51 09:33:53

Q. Okay. Now, let's just go back to Exhibit 565. And let me direct your attention to Exhibit A to the deposition notice, which is -- and we'll call it Bates number, those are the numbers at the bottom -- Bates Number 107. We'll just take the last three numbers. Do you see that? 09:33:55 09:33:59 09:34:05 09:34:08 09:34:12 09:34:13

A. Yes. 09:34:15

Q. Okay. The first category is, "Any and all writings regarding this action, or any issue in it, any of the parties to this action, environmental tobacco smoke, or any constituent thereof, claimed health consequences or risks of environmental tobacco smoke, or warnings, actual or proposed, regarding tobacco smoke, including environmental tobacco smoke." Have you brought with you all documents that you have in your file regarding those subjects? 09:34:15 09:34:18 09:34:21 09:34:24 09:34:27 09:34:30 09:34:32 09:34:39 09:34:39

A. No. I still have some literature that would pertain to some of this that I have not yet reviewed. 09:34:42 09:34:42 09:34:44

Q. Okay. Which literature is that? 09:34:45

A. It would be literature concerning passive smoking. I mean I literally have not looked at all the files. So I don't know what -- what it -- what it includes. 09:34:50 09:34:52 09:34:54 09:34:55

Q. Could you tell me a little bit more specifically what that literature might be? 09:34:56 09:34:57

A. Yes. It would be references that might have been cited in the Cal EPA report. It would be references that may have come from a lit review that I have run, a computer search. And some of those would relate to cardiovascular disease. 09:35:00 09:35:03 09:35:06 09:35:09 09:35:16

Q. Do they relate to anything other than cardiovascular disease? 09:35:23 09:35:25

A. Yes. Many of them would relate to other -- possible ill health effects of exposure. 09:35:26 09:35:29

Q. All right. Now, do you actually have copies of additional studies that are not reflected in 564 or -- 09:35:34 09:35:35 09:35:38

A. I --

Q. -- 565? 09:35:39

A. I am not sure, but I believe so. And I may yet have that in before this is done. That is, there are some that are not yet in, and they would not be here then. 09:35:40 09:35:43 09:35:46 09:35:50

Q. Okay. Approximately how many studies do you have in this current literature review that you're doing? 09:35:52 09:35:54 09:35:56

A. Oh, maybe a dozen in the heart disease and 09:35:58

cardiovascular disease. I've received a lot. So -- 09:36:01
I'm not sure on the other, but maybe three or four 09:36:09
dozen in the other general category. Those are very 09:36:11
rough estimates. I haven't counted it. 09:36:15
Q. Three to four dozen you think you have in 09:36:17
the other categories? 09:36:19
A. Uh-huh. 09:36:20
Q. Do you have all of those right now in hard 09:36:21
copy form? 09:36:24
A. No. Some of those I have only in abstract. 09:36:25
Some I have a reference, and they're still being 09:36:27
sought from the library. 09:36:30
Q. Who is seeking those? 09:36:31
A. My research assistant. 09:36:32
Q. Is it someone who works for you? 09:36:34
A. Correct. 09:36:37
Q. Who is that? 09:36:37
A. Mark Adams, I believe is his name. 09:36:37
Q. Is he a graduate student? 09:36:39
A. Undergraduate student. 09:36:41

Q. Now, you said that you ran a literature 09:36:43
review. What type of literature review did you run? 09:36:45
A. Actually, Mark ran it, and it was a 09:36:50
computer search of the Med Line and related 09:36:52
literature. 09:36:55
Q. What was he looking for? 09:36:59
A. Studies related to ETS passive smoking, 09:37:00
other forms of tobacco exposure. 09:37:07
Q. Does he have anything in writing that 09:37:13
indicates the review that he did? 09:37:17
A. No. I asked him to do it. I don't -- I 09:37:22
don't know if he has anything in writing. He may 09:37:23
have written something down as he went to the library 09:37:24
or went to the computer for it. But not to my 09:37:27
knowledge. 09:37:30
Q. Does he have a computer printout of the 09:37:30
documents that he found on Med Line? 09:37:32
A. I have that. 09:37:35
Q. You have a -- 09:37:36
A. I have that. 09:37:37
Q. -- computer printout of the list of the 09:37:38
documents? 09:37:40
A. That's part of the abstract list that I was 09:37:40
referring to, yeah. 09:37:43
Q. All right. Is that contained in either 09:37:43
Exhibit 564 -- 09:37:45
A. No, that would still be at home.
Q. -- or 565? 09:37:46

A. I was bringing in -- pardon me. I was 09:37:47
bringing in the references that I obtained rather 09:37:48
than the list. So I have that at home. 09:37:50
Q. How long a list is that? 09:37:54
A. I'm not sure. It's probably a half-inch 09:37:56
thick, printed documents. 09:37:59
Q. Of printed documents, or the list of 09:38:02
documents? 09:38:04
A. References. It would be either a reference 09:38:05
and/or reference in abstract, depending on what was 09:38:08
obtainable. 09:38:13
Q. Okay. And the references from the Cal EPA 09:38:13
report, is there a list of those references that 09:38:16

you're looking up? 09:38:19
A. No. 09:38:21
Q. How are you identifying which references you're looking for? 09:38:22 09:38:24
A. I've -- I've been -- some I've gotten from the attorneys, and some I go for. As I read an article, and it looks like it's a critical article to answer some question that might occur to me, then I would try to find that and look for it so that I could study it firsthand. 09:38:26 09:38:28 09:38:30 09:38:36 09:38:39 09:38:40
Q. But you haven't prepared any list of the documents -- 09:38:47 09:38:50
A. No. 09:38:50
Q. -- that you're -- 09:38:50
A. No. You're presuming a level of 09:38:51

organization I don't have. 09:38:54
Q. We've got to be careful about speaking at the same time. I know it's -- I know it's hard, but we're going to drive our reporter crazy, and I don't want to get her mad at me because I have to see her again. 09:38:56 09:38:58 09:39:00 09:39:04 09:39:06
All right. So you don't have any list at all of the Cal EPA references? 09:39:09 09:39:11
A. Only in the -- in the report. I don't have a separate list. 09:39:13 09:39:14
Q. Okay. What other research do you intend to do? 09:39:15 09:39:19
A. Now, that's all. I mean if I'm asked to do something else, I may take that under consideration. 09:39:21 09:39:24
Q. Now, you mentioned that the lawyers have also provided you with some references? 09:39:26 09:39:28
A. Yes. 09:39:31
Q. Does Exhibit 564 and 565 contain all of the references that the lawyers have provided to you? 09:39:31 09:39:35
A. I don't know, but I don't think so. I haven't -- I haven't looked at the 565. I believe that's 565. Yes. Yes, that's part of 565. I haven't looked at this bibliography yet to know what I already have, what I do not yet have and should look for. And there may be some articles they have sent me which I've not yet reviewed and, therefore, do not know much about them. I don't know whether I have them or not until I've actually looked at them. 09:39:39 09:39:41 09:39:45 09:39:51 09:39:55 09:39:59 09:40:02 09:40:05 09:40:08

Q. Now, what I wanted to know specifically is whether or not Ms. Frostrom, or someone in her firm, has provided you with something that is not reflected in either Exhibit 564 or 565. 09:40:14 09:40:17 09:40:20 09:40:24
A. It is possible they have provided me something that's not here. I would have to go home and check the copies I have at home to determine that. 09:40:28 09:40:30 09:40:32 09:40:35
Q. All right. What is it that you have at home? 09:40:37 09:40:38
A. Like this. I have the actual copies of some of these kinds of articles. And they may not -- they may include articles that is more than this set here. I'd have to match this to that to determine that for sure. 09:40:39 09:40:41 09:40:46 09:40:48 09:40:50
Q. And that's everything that you have at home? 09:40:52 09:40:53
A. Uh-huh. 09:40:53

Q. All right. When did you first become involved in this case? 09:40:56 09:40:57
A. I'm not sure. It was probably about a month ago, when Karen Frostrom called and asked if I would be interested in assisting. And there were two or three phone calls that ensued, at the conclusion of which I agreed to serve in this capacity. 09:41:03 09:41:05 09:41:09 09:41:14 09:41:17
Q. You think that was about a month ago? 09:41:21
A. A month or six weeks, I'm not sure. 09:41:23
Q. Was Ms. Frostrom who first called you? 09:41:27

A. Yes. 09:41:30
Q. Do you know how she got your name? 09:41:30
A. No. 09:41:32
Q. Did anyone recommend you to her? 09:41:36
A. I do not know that. I don't know how she found me. 09:41:40 09:41:42
Q. Have you ever talked with anybody at her firm about how they found you? 09:41:43 09:41:45
A. No. 09:41:47
Q. No one ever told you how they found you? 09:41:48
A. No. 09:41:50
Q. How much time have you spent on this case since you first became involved in the case? 09:41:52 09:41:56
A. Many times what I thought it would require. I haven't added it up. I've been too busy working on it to actually construct a tally of hours yet. So I couldn't tell you. But it's been a lot of time between the initial call and today's date. I spent all of this weekend preparing just for this morning. 09:42:00 09:42:05 09:42:09 09:42:13 09:42:16 09:42:21
Q. If we were to make an estimate of the number of hours that you spent, would it be more than 100 hours or less than 100 hours? 09:42:26 09:42:28 09:42:30
A. Oh, probably less than 100 hours. 09:42:35
Q. Would it be more than 50 hours? 09:42:38
A. No. It would probably be closer to 50 than more than 50. 09:42:42 09:42:44
Q. All right. So in the approximate -- let's say approximately 50 hours that you spent on this 09:42:45 09:42:49

case, what generally have you done? 09:42:51
A. A lot of what I've -- 09:42:59
MS. FROSTROM: Objection; vague and ambiguous. 09:42:59 09:42:59
THE WITNESS: Okay. I have -- 09:43:07
BY MR. CAFFERTY:
Q. One thing I should tell you is that Ms. Frostrom may make objections from time to time, and she's doing that typically just for the record. Unless she instructs you not to answer, you're free to answer -- 09:43:08 09:43:10 09:43:13 09:43:15 09:43:19
A. Okay.
Q. -- the question. 09:43:19
So if you could tell me generally what you have done during the 50 or so hours that you've worked on it. 09:43:20 09:43:23 09:43:25
A. Okay. A lot of what I've done has been collecting the materials, and in the collection of those materials, trying to organize them for review. And in and around that process I've also had one meeting with Mr. McGuire, at which Karen was present for part of it. And I think I've had one office meeting with Karen in addition to that. Couple of 09:43:27 09:43:28 09:43:31 09:43:34 09:43:40 09:43:46 09:43:50

e-mail exchanges. Maybe more, two or three. And there may have been one or two phone calls involved in that. Mostly what I've been doing is trying to read the information, make sense of it. 09:43:56 09:44:03 09:44:06 09:44:09

Q. And which information have you been trying to read? 09:44:13 09:44:17

A. The literature. The Cal EPA reports and the literature that's related to that, both that was cited in it, and also literature that may be pertinent that's been published since that report. 09:44:17 09:44:21 09:44:24 09:44:26

Q. Had you read the Cal EPA report previously? 09:44:32

A. No. 09:44:35

Q. When did you first read it? 09:44:35

A. Gosh, it would have been within a week or so of agreeing to start the -- the assistance for this project, for this case. 09:44:38 09:44:41 09:44:44

Q. What literature is it that you have been reading? 09:44:46 09:44:49

A. I've been trying to read the literature that is predominantly people epidemiology concerning ETS and its effects on health. 09:44:49 09:44:51 09:44:55

Q. Which health end points have you been reviewing literature for? 09:45:01 09:45:03

A. Pretty much all of them. I haven't been formally selecting out certain health end points, with the exception that I did look at -- I spent a little time looking at the cardiovascular disease end points. 09:45:05 09:45:07 09:45:10 09:45:13 09:45:16

Q. Could you give me a list of all of the health end points for which you've been reviewing epidemiological literature. And all of this is epidemiological literature that you're looking at; is that correct? 09:45:19 09:45:22 09:45:24 09:45:28 09:45:37

A. I have a hard time answering that because I view that as all science. So if it was an animal study and I happened to find it, I might have reviewed it. If it were a people study, I would have reviewed it. 09:45:37 09:45:37 09:45:37 09:45:40 09:45:40

Q. All right. So if you say "people," that would mean an epidemiology -- 09:45:42 09:45:43

A. Many --

Q. -- study? 09:45:45

A. Many would refer that -- depending on its design, many would call that an epidemiological study. Many would not call an animal study such. That has to do with some discriminations about how you classify science. And -- 09:45:46 09:45:50 09:45:54 09:45:57 09:45:59

Q. All right. Well -- 09:46:03

A. I tend --

Q. -- let's --

A. -- I tend to classify it broadly. 09:46:03

Q. I apologize. 09:46:06

A. That's all right. 09:46:07

Q. I thought you were done. 09:46:08

All right. Okay. Well, let's -- let's -- let's talk about the people epidemiology studies first. 09:46:10 09:46:12 09:46:15

A. Okay. 09:46:16

Q. What people epidemiology literature have you been reviewing? And I mean by that what end points have you been looking at? 09:46:16 09:46:20 09:46:24

A. Well, I'm not sure I could give you a complete list because I haven't been focusing on the specific outcomes as a basis for my review, except for those that were concerned with cardiovascular disease. I know I have reviewed some that pertained to pulmonary function, such as lung cancer. I've used -- I've looked at others that may have had other outcomes, such as asthma exacerbation. And then the cardiovascular disease, of course, that I just mentioned. 09:46:26 09:46:27 09:46:30 09:46:33 09:46:36 09:46:37 09:46:42 09:46:45 09:46:52 09:46:56

This is a little difficult because I do some of the same review in my normal work. So -- although not to the same extent, not with the same focus. It would come up from time to time in the work I do for passive smoking research in general. 09:46:56 09:46:58 09:47:01 09:47:03 09:47:06

Q. All right. What I'd like to get is a complete list of all the health end points that you -- for which you have been reviewing people epidemiology literature since you became involved in this case. 09:47:11 09:47:14 09:47:16 09:47:18 09:47:22

A. I could produce that. I can't give it to you completely here because I can't remember it all. I haven't been thinking about it in that form. If that's something critical to write down, I could write that down. 09:47:23 09:47:25 09:47:27 09:47:30 09:47:33

Q. If you could do your best today -- 09:47:33

A. Okay.

Q. -- that would be helpful for me. 09:47:35

A. It would include -- 09:47:37

Q. Recognizing that you --

A. -- pulmonary disease -- 09:47:37

Q. All right.

A. -- and cardiovascular disease would be the two big end points. That would include both illness and death outcomes. 09:47:39 09:47:41 09:47:47

Q. Have you looked at any people epidemiology associating ETS exposure with reproductive outcomes? 09:47:59 09:48:04

A. Not specifically. 09:48:08

Q. Prior to your involvement in this case, had you reviewed people epidemiology literature for cardiovascular disease and ETS exposure? 09:48:11 09:48:14 09:48:17

A. Not to the same extent, but yes. 09:48:23

Q. What do you mean by "not to the same extent"? 09:48:26 09:48:28

A. When I do my studies, I'm usually looking to summarize the literature on probable health effects. And then my concentration tends to be on how one would intervene to change exposure or how one would intervene to change tobacco use. In this instance, I'm concentrating more on the anal -- the assessment of the research that concerns health effects. It's a different emphasis. 09:48:28 09:48:30 09:48:35 09:48:39 09:48:42 09:48:46 09:48:48 09:48:52

Q. Prior to your involvement in this case, had you reviewed studies regarding cardiovascular disease and ETS exposure for purposes of an assessment of those studies? 09:48:57 09:49:00 09:49:05 09:49:09

A. No. 09:49:10

Q. Prior to your involvement in this case, had you reviewed people epidemiology literature for the purpose of assessing the relationship between ETS 09:49:12 09:49:14 09:49:19

exposure and pulmonary disease? 09:49:26
A. To some extent, yes. 09:49:29
Q. And what is the extent to which you had reviewed it? 09:49:32 09:49:33
A. We have looked at the relationships between passive smoking exposure and asthma, and pulmonary compromise in children particularly. That would include such things even as otitis media, not limited to strict pulmonary conditions. 09:49:34 09:49:36 09:49:44 09:49:49 09:49:53
Q. Is there any other pulmonary disease literature that you had assessed prior to your involvement in this case? 09:50:01 09:50:04 09:50:08
A. Well, in general I'm familiar with cystic fibrosis; although I've not assessed it in this case at all. 09:50:09 09:50:12 09:50:15
Q. Do you intend to assess cystic fibrosis in this case? 09:50:16 09:50:20
A. No, not unless asked. It's a pretty rare disease. 09:50:21 09:50:25
Q. Prior to your involvement in this case, had you assessed the lung cancer and ETS exposure people epidemiology literature? 09:50:25 09:50:26 09:50:31
A. Not in detail. 09:50:33
Q. Are you in the process of doing that now? 09:50:37

A. As a general background to the Cal EPA report, yes. 09:50:39 09:50:42
Q. What do you mean by "general background to the Cal EPA report"? 09:50:43 09:50:45
A. What I have done is I've taken some of the reference from the Cal EPA report, or from literature that's been published since, and reviewed some of those specific studies myself. In effect, redoing some of what the investigators did when they constructed the Cal EPA report. Although I have not done as thorough a job as what that report represents. 09:50:47 09:50:49 09:50:52 09:50:54 09:50:59 09:51:01 09:51:04 09:51:12
Q. Okay. And what is -- what is your purpose in doing that review? 09:51:12 09:51:12
A. For my -- my purpose is to use my judgment to check what others have said about a particular study. Rather than accept their statements about it, I have reviewed it myself. 09:51:12 09:51:16 09:51:17 09:51:20
Q. Have you completed your review? 09:51:22
A. No. 09:51:23
Q. Have you completed -- and that was your review for lung cancer. You haven't completed your review for lung cancer? 09:51:23 09:51:25 09:51:28
A. Correct. I -- I -- unless -- if I have, I don't know that because I need to first find out if there are studies I have missed. If I think I have all the studies that are pertinent, then it is done. 09:51:29 09:51:31 09:51:33 09:51:36
Q. Have you completed your review for 09:51:38

cardiovascular? 09:51:42
A. No. 09:51:43
Q. Have you completed your review for any health end point? 09:51:43 09:51:46
A. No. 09:51:47
Q. When do you intend to complete your review? 09:51:47
A. As soon as possible. I don't know the exact length of time that's going to take, because I'm doing this in and around my other work. So it 09:51:50 09:51:52 09:51:53

has not not been possible to devote continuous time to this. 09:51:56 09:52:01

Q. What's your best estimate as to when you'll be completed with your analysis? 09:52:01 09:52:02

A. Two to three weeks. 09:52:06

Q. Have you been paid by plaintiffs for any of the time that you spent on this case? 09:52:18 09:52:20

A. I've received a retainer for one day. 09:52:22

Q. How much was that for? 09:52:25

A. $800.

Q. Who paid that money to you? 09:52:27

A. I received the check from the plaintiff's attorney. 09:52:28 09:52:31

Q. And who is it that wrote the check to you? 09:52:32

A. I think it was the attorney's office, but I don't know. I didn't look. 09:52:35 09:52:37

Q. What is your billing rate? 09:52:40

A. I'm currently charging $100 an hour. 09:52:42

Q. How many times have you billed clients at that rate? 09:52:45 09:52:47

A. I have not billed them at all yet. 09:52:48

Q. Any clients. I'm not talking about this specific client -- 09:52:51 09:52:52

A. Oh, I'm sorry.

Q. -- but any clients. 09:52:53

A. Gosh, I don't know. My consulting rate varies depending on the nature of the work. With consulting for, say, an NIH research grant, it might be closer to 3- to $500 a day. If it were a large commitment to an NIH grant, then it may be computed more on a percent time basis, such as 10 percent FTE. And I have consulting arrangements like that now with other investigators across the country. 09:52:56 09:52:59 09:53:03 09:53:07 09:53:16 09:53:21 09:53:24 09:53:27

Q. What do you mean by "10 percent FTE"? 09:53:30

A. 10 percent of my full-time equivalent salary for an annualized period. 09:53:33 09:53:35

Q. Would that be based on your salary as a professor at -- 09:53:39 09:53:42

A. Correct.

Q. -- San Diego State? 09:53:42

A. Correct. 09:53:44

Q. So it would be 10 percent of your full-time equivalent for the time that you spent working on -- 09:53:44 09:53:46

A. Correct. 09:53:49

Q. All right. And what is the nature of your consulting practice today? 09:53:52 09:53:53

A. Right now I have been doing consulting locally for a project looking at evaluating domestic violence, recovery program for domestic violence victims. I've also done some consulting for a research study in Minnesota. And I have done some with a similar research study in Memphis. I'm in discussions with one that may or may not go forward in Boston. 09:53:55 09:53:57 09:54:05 09:54:09 09:54:12 09:54:16 09:54:23 09:54:25

Q. In where? 09:54:26

A. Boston, I believe. 09:54:26

Q. What is the Minnesota research study about? 09:54:28

A. They're looking -- they have been funded by NIH to examine a counseling procedure to reduce passive smoking exposure in children who are members of families funded by a large HMO in Minneapolis -- 09:54:33 09:54:36 09:54:39 09:54:43

not funded by, but treated by. 09:54:49
Q. Who's funding that study? 09:54:51
A. National Institutes of Health. 09:54:53
Q. And what is the funding level for that? 09:54:58
A. I am not sure. It's part of a large center 09:54:59
grant. So it would be millions of dollars. I don't 09:55:02
know if it's 2 or 3million. I don't know how large. 09:55:05
Q. What do you mean by a "center grant"? 09:55:08
A. It's a -- it's a mechanism that NIH uses to 09:55:10
fund a collection of studies in one package, and so 09:55:13
there would be multiple investigators involved. In 09:55:17
this case I'm working with one of the investigators, 09:55:20
but not the principal investigator, for the overall 09:55:23
center grant at Minneapolis. And I don't actually 09:55:26

know the size and scope of the overall center. I've 09:55:31
not seen that. 09:55:33
Q. Okay. And what is your role in that 09:55:35
research project? 09:55:36
A. I'm serving as a consultant to advise them 09:55:36
on measurement of ETS, measurement of possible 09:55:39
correlates of ETS, and on the development of and 09:55:47
implementation of a counseling program to reduce 09:55:50
exposure in the children that are in the experimental 09:55:53
condition. 09:55:58
Q. How much are you being paid for your 09:55:59
consulting work? 09:56:00
A. 10 percent FTE. 09:56:02
Q. What does that come out to be? 09:56:04
A. Approximately $15,000. 09:56:05
Q. For how many hours? 09:56:07
A. It's for 10 percent of my time for one 09:56:10
year. 09:56:12
Q. Oh, all right. So 10 percent FTE is 09:56:13
measured on an -- 09:56:17
A. Annualized basis. 09:56:19
Q. -- annualized basis?
A. That's correct. 09:56:20
Q. So how much time will you spend working on 09:56:20
that study this year, approximately? 09:56:26
A. I've already spent more than 10 percent of 09:56:26
my time on that study this year. 09:56:26
Q. How does that compare to your $100-per-hour 09:56:30

billing rate for this case? 09:56:32
A. I have never done the conversion, but I 09:56:34
think the $100 billing rate is less, at least less 09:56:35
total income. I don't know what I make on a daily 09:56:39
basis. I've never computed it. 09:56:41
Q. All right. And you also mentioned that 09:56:44
you're involved in a Memphis study. What's the 09:56:45
Memphis study? 09:56:48
A. Memphis study is with the medical center. 09:56:49
It's actually with St. Jude's Hospital. And they 09:56:52
have proposed a study to be funded by NIH which would 09:56:55
look at the reduction of passive smoking exposure in 09:56:59
children who have cancer. And that study is under 09:57:02
review by NIH now. I've been paid I think a thousand 09:57:05
dollars for consulting in the front end of that to 09:57:10
help them with the proposal. If it's funded, then, 09:57:13
again, I would serve in a capacity approximating 10 09:57:16
percent of my annualized time. That -- that won't be 09:57:20
funded for approximately eight or nine more months, 09:57:23

maybe a year, if funded at all. 09:57:28
Q. How is that study being performed? 09:57:32
A. I don't understand your question. 09:57:34
Q. What is the study protocol? 09:57:36
A. The study will look at children who have cancer. And those children will be -- and who are also exposed to their family's cigarette smoke. And then a group of the children will receive counseling, their families will receive counseling, in order to 09:57:39 09:57:41 09:57:44 09:57:49 09:57:53

reduce the exposure that might now be taking place from their parents smoking. A comparison group will receive either an alternate intervention or no intervention, and I can't remember which now. And then there'll be a comparison made to see if the counseling program successfully reduces passive smoke exposure. 09:57:56 09:57:59 09:58:03 09:58:07 09:58:09 09:58:12 09:58:16
Q. What will your role be in that study? 09:58:17
A. My role will be similar to that of Minnesota. I will advise them on some of the measurement procedures, the research design, and also the intervention procedures. 09:58:19 09:58:22 09:58:25 09:58:27
Q. What is the Boston study about? 09:58:28
A. The Boston study is an asthma study. It is only a study in brainstorming phase at this point. And that's looking at the use of a telephone mediated automated counseling procedure for asthma. They call it TLC, I suppose to take advantage of the tender loving care analogy. 09:58:32 09:58:36 09:58:38 09:58:48 09:58:51 09:58:56
At any rate, what it's looking at is to see if asthma management can be enhanced by an automated counseling system where patients' families would be called, and the families would be advised on the best means of taking care of their children who have asthma. That covers a wide range of events, everything from proper medication, consumption or compliance with drug taking, to reduction in exposure to pet dander and other triggers of asthma, 09:58:58 09:59:02 09:59:04 09:59:08 09:59:10 09:59:12 09:59:16 09:59:18 09:59:23

including, but by no means, primarily emphasizing passive smoking exposure. 09:59:26 09:59:29
Q. What will your role be in that study? 09:59:33
A. My role there, again, will be for design, some measurement issues. Less so on the intervention, because the intervention has largely been designed by my colleagues in Boston. Although I will probably have some role in recommending refinements in the intervention. 09:59:36 09:59:39 09:59:42 09:59:44 09:59:48 09:59:49
Q. Has that study been funded yet? 09:59:52
A. No. It hasn't even been written yet. 09:59:53
Q. Have you been paid anything for that study? 09:59:56
A. No. 09:59:58
Q. You also mentioned a study about domestic violence. What was that about? 09:59:59 10:00:02
A. There's a local group here and, I'm sorry, I can't give you the exact name, that is funded to assist women who are victims of violence. And there are a number of nonprofit shelters where women can be assisted by social services, social work case management services, as well as, in some cases, provided temporary sheltered housing. And the current evaluation is to assess the Victims of Crime Fund provision of financial resources, in concert 10:00:04 10:00:06 10:00:09 10:00:13 10:00:19 10:00:24 10:00:27 10:00:31 10:00:38

with the case management services, to see if that system, that combined service, shows promise and should be institutionalized as a combined service for women who have been victims of violence. 10:00:42 10:00:45 10:00:49 10:00:54

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Q. Does that work have anything to do with ETS? 10:00:58 10:01:01

A. Not to my knowledge, no. 10:01:01

Q. By the way, when you get paid this 10 percent FTE -- 10:01:02 10:01:04

A. Uh-huh.

Q. -- does that go to you, or does that go to the university? 10:01:05 10:01:07

A. That goes to me as a consultant. 10:01:08

Q. Okay. All right. Is there any other consulting that you're currently doing? 10:01:11 10:01:15

A. Not -- no, not that -- I don't believe so. I can't think of anything else. 10:01:20 10:01:22

Q. All right. How did you determine the $100-per-hour billing rate for this case? 10:01:24 10:01:27

A. Karen caught me off guard, and I made the decision quickly on the telephone. That may be the wrong thing to say under these conditions. I normally do not charge nonprofit corporations what I would charge a profit-making corporation. So I have two -- two negotiable fees in that regard. This would be my lowest fee, as a function of nonprofit status. 10:01:30 10:01:37 10:01:39 10:01:41 10:01:45 10:01:50 10:01:52 10:01:56

Q. And is that because AESI -- 10:01:57

A. Correct.

Q. -- American Environmental Safety Institute is considered to be a nonprofit company? 10:02:00 10:02:02

A. Correct. 10:02:04

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Q. Okay. What would your billing rate be for a profit-making company? 10:02:04 10:02:06

A. A minimum of 200 an hour. 10:02:07

Q. And what profit-making companies have you done consulting work for? 10:02:09 10:02:11

A. I haven't done any recently. And the last time I had an opportunity it was for an attorney in Louisiana, and that did not work out. 10:02:13 10:02:16 10:02:19

Q. What kind of work were you doing for the attorney in Louisiana? 10:02:21 10:02:23

A. He had approached me for possibly serving in the same -- 10:02:24

MS. FROSTROM: I would object to the extent this calls for work product. If he was a consultant, not designated as an expert, this might be protected information. 10:02:25 10:02:27 10:02:30 10:02:35

THE WITNESS: I don't know if it's protected or not. I don't mind saying. But it was to serve as an expert witness. But that did not occur. He did not contract with me, so it did not happen. So it was a non-job. 10:02:36 10:02:37 10:02:38 10:02:42 10:02:46

BY MR. CAFFERTY:

Q. Okay. But that would have been for $200 per hour? 10:02:48 10:02:50

A. Uh-huh. 10:02:52

Q. And what type of expertise was involved in that case? 10:02:52 10:02:54

A. That was a case regarding the Dow Chemical 10:02:56

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breast implants. And I was, again, being asked to consider the epidemiology of the research concerning possible ill health effects for the implants. 10:03:01 10:03:04 10:03:08

Q. Would you have been a consultant for Dow Chemical or for plaintiffs in that case? 10:03:11 10:03:16

A. Plaintiffs. 10:03:18

Q. But you never really were retained to do that work? 10:03:18 10:03:21

A. No. 10:03:21

Q. Have you ever billed anyone $200 per hour for your time? 10:03:21 10:03:24

A. No. 10:03:25

Q. Is anyone else associated with you working on this case? 10:03:26 10:03:29

A. Say that question again. 10:03:32

Q. Is anyone else associated with you working on this case? We mentioned -- 10:03:34 10:03:36

A. Yes.

Q. -- one person before. 10:03:38

A. Yes. 10:03:39

Q. Mark -- what was his last name? 10:03:40

A. I think it's Adams. He's a research assistant in my office. I also have my secretary in my office, who's assisted me with some of the scheduling and receipt of faxes and so forth. 10:03:41 10:03:44 10:03:46 10:03:49

Q. Did they get paid for their work on this case? 10:03:51 10:03:54

A. They will. They have not yet. 10:03:55

Q. And is that included in your $100 -- 10:03:56

A. Yes. 10:03:58

Q. -- per hour fee? 10:03:58

A. Yes. 10:04:00

Q. All right. So you pay them out of your $100? 10:04:00 10:04:02

A. Correct. 10:04:02

Q. Is there anybody else who's going to be working with you on this case? 10:04:02 10:04:04

A. Not -- not so far. Unless I need some extra -- some specialty background that I'm not now familiar with. 10:04:05 10:04:08 10:04:11

Q. Okay. Now, what work have you specifically been asked to do in this case? 10:04:12 10:04:14

A. I've been asked to review the literature, and to particularly review the research methods that have been involved in the literature that's been cited in the Cal EPA report, and that that may have come since then. 10:04:18 10:04:20 10:04:23 10:04:29 10:04:32

Q. Let's go back to Exhibit 564, which is the larger group of documents. And I'd like to direct your attention specifically to exhibit -- or excuse me -- Document Number 56, which is kind of in the middle of that stack of stuff. Probably a better idea. 10:04:38 10:04:48 10:04:51 10:04:58 10:05:02 10:05:13

A. Yes. Okay. 10:05:15

Q. All right. Do you have that in front of you? 10:05:16 10:05:18

A. I do. 10:05:18

Q. All right. Now, this references a summary of a meeting 6-23 -- 10:05:19 10:05:20

A. Uh-huh.

Q. -- 00. Is this an e-mail that you 10:05:23

prepared? 10:05:25
A. Yes. 10:05:26
Q. And you sent it to Mr. McGuire and Ms. Frostrom? 10:05:27 10:05:29
A. Uh-huh. 10:05:30
Q. Was the meeting -- this -- this e-mail appears to relate to a meeting that occurred on June 23rd, 2000, correct? 10:05:32 10:05:35 10:05:38
A. It was in relation to that meeting. I can't remember the exact date. But that's about right. 10:05:42 10:05:42 10:05:43
Q. Now, was that your first meeting -- 10:05:44
A. Yes. 10:05:46
Q. -- with this -- with the lawyers in this case? 10:05:46 10:05:48
A. Yes, that was the first meeting. 10:05:49
Q. All right. Had you spoken with them on the phone prior to that time? 10:05:51 10:05:53
A. Yes, I had. 10:05:55
Q. How many times? 10:05:55
A. Two or three times. 10:05:55
Q. All right. What had you talked about prior to this meeting? 10:05:55 10:05:58

A. Just generalities. Such things as would I be willing to serve in this capacity and what they would like, somebody with an epidemiology background to speak to the research methods involved. And I thought I could do that. And so this meeting was to obtain the details. 10:05:58 10:06:01 10:06:04 10:06:06 10:06:09 10:06:13
Q. Which details were you -- 10:06:16
A. Of what they would like me to do. 10:06:17
Q. Okay. All right. Now, when I look at the next page, which is the second page of the e-mail, it's Bates stamped 57. 10:06:19 10:06:22 10:06:25
A. Uh-huh. 10:06:29
Q. It says, "Finally, I will set up my files to follow the dates as you instructed." What does that mean? 10:06:31 10:06:34 10:06:36
A. What -- what I -- if I remember correctly, what I was advised to do, to set up the files of any information that comes in by date. I have actually not yet done that, because I haven't had the time to organize my files yet. But I will eventually do that. So as I -- as I work through the materials, I'll try to do it by time specific events. 10:06:38 10:06:39 10:06:48 10:06:48 10:06:48 10:06:51 10:06:55
Q. All right. Then in the paragraph above that it says, "I have some very limited notes taken while in the meeting and will make them available to you and the defendants as instructed." Do you see that? 10:06:59 10:07:00 10:07:04 10:07:06 10:07:08
A. Uh-huh. 10:07:08

Q. All right. Do you have such notes? 10:07:09
A. They were -- I'm not sure if I still have them myself actually. But they were -- 10:07:10 10:07:13
Q. Okay. Let me show you exhibit -- or page 49, which I think -- 10:07:15 10:07:18
A. Okay.
Q. -- may be those notes. 10:07:19
A. Yes. 10:07:19
Q. And that's what I'm really trying to ascertain. 10:07:20 10:07:22

A. Yeah, thank you. That helps, actually. 10:07:23
Yes, those are the notes. 10:07:25
Q. All right. Those are the notes from your 10:07:26
first meeting -- 10:07:27
A. Uh-huh. 10:07:29
Q. -- on June 23rd? 10:07:29
A. Uh-huh. 10:07:31
Q. Since that meeting on June 23rd, I believe 10:07:32
you mentioned you had a second meeting; is that 10:07:33
correct? 10:07:36
A. I had a second meeting with Karen. 10:07:36
Q. When did that meeting occur? 10:07:38
A. A week ago I believe, approximately. 10:07:40
Q. What was the purpose of that meeting? 10:07:44
A. To tell me about this deposition. To give 10:07:45
me instructions regarding the deposition. 10:07:48
Q. All right. Now, I see from the meeting 10:07:50
notes, which is Bates Number 49, part of Exhibit 564, 10:07:51
55
that the meeting looks like it occurred from 12:30 to 10:07:59
4:15. Is that what that indicates at the top -- 10:08:01
A. Yes.
Q. -- of the page? 10:08:04
A. Yes. 10:08:06
Q. It's about three hours and 45 minutes -- 10:08:07
A. Uh-huh.
Q. -- for that meeting. How long did the 10:08:10
second meeting last with Ms. Frostrom? 10:08:11
A. That was a 9:30 meeting, and I think I left 10:08:15
there about 12:45. So most of the morning. 10:08:17
Q. Okay. All right. And are those the only 10:08:21
two meetings that you've had with -- 10:08:23
A. Correct. 10:08:25
Q. -- the lawyers in this case? 10:08:25
A. Uh-huh. 10:08:27
Q. Have you had any other telephone 10:08:27
conversations following your June 23rd meeting? 10:08:29
A. No. There's been a couple of fax 10:08:33
communications, such as the reference list that was 10:08:35
in this 565 document. I think -- I think I received 10:08:38
by fax or by mail the instructions for how to find 10:08:45
this office. I think that's it. 10:08:48
Q. All right. Let's go through these meeting 10:08:53
notes, because I want to see if you can help me 10:08:57
decipher your handwriting. Obviously, it's always 10:08:59
hard to read somebody else's handwriting.
A. You'll find this difficult to believe, but 10:09:01
56
sometimes I have difficulty deciphering my 10:09:04
handwriting too. But I'll do my best. 10:09:07
Q. I don't find that hard to believe at all. 10:09:09
I have the same problem. 10:09:12
The first line says, "Meeting notes of 10:09:13
6-23-2000," and the second line says "12:30 to 4:15." 10:09:16
Those are easy. Then it says on the left, and 10:09:20
there's kind of a hole punched here, looks like 10:09:22
"Client - American" -- 10:09:25
A. Yeah.
Q. -- "Environmental Safety Institute, 10:09:28
Non-profit." Is that what that says? 10:09:29
A. Correct. 10:09:31
Q. All right. And what is that referring to? 10:09:32
A. That's referring to the plaintiff in this 10:09:33

case, as was explained to me at the meeting. 10:09:35
Q. All right. Now, underneath "client" 10:09:38
there's some reference there, and I can't really tell 10:09:39
what that says. "CO" something, "Bill defendants CO 10:09:41
depositions." 10:09:47
A. Yeah.
Q. What does that mean? 10:09:47
A. I believe, if I'm remembering correctly, 10:09:49
that I was to bill the attorney -- pardon me -- the 10:09:51
defendants in care of the attorney. So I will be 10:09:56
sending my -- my charges to Mickey McGuire. 10:09:58
Q. Okay. And then what does "bill defendants 10:10:04
CO depositions" mean? 10:10:05

A. I'm not sure. At this point I don't 10:10:11
remember. I had -- my -- my understanding of the 10:10:13
billing procedure now is that I am to bill the time 10:10:17
that I charge to Mr. McGuire, but that the defendants 10:10:20
will be paying that bill. 10:10:24
Q. All right. Now, under -- there's a series 10:10:27
of items here, 1 to 15. I want to see if we can take 10:10:31
those individually. What does Number 1 say? 10:10:34
A. "Take notes re: Conversations with 10:10:38
McGuire." 10:10:39
Q. What does that mean? 10:10:41
A. Probably that's a note to myself that I 10:10:43
should be taking notes. I tend to do that as a 10:10:45
routine in -- in business meetings that I'm involved. 10:10:49
My memory isn't so good, so I tend to jot down notes. 10:10:53
That was probably just a note to myself. Otherwise, 10:10:57
I don't know. 10:11:00
Q. Did Mr. McGuire tell you anything about 10:11:00
taking notes? 10:11:02
A. No. You know, he has since asked me to 10:11:04
limit my communications to the material that's 10:11:08
pertinent to this case. I did send him an e-mail 10:11:11
about a totally different issue, and he didn't want 10:11:15
that to get confused with that. But that was a 10:11:18
subsequent conversation after this meeting. 10:11:22
Q. What was the e-mail that you sent to him 10:11:24
that was about a different subject? 10:11:26
A. Oh, gosh, I don't have that in front of me. 10:11:27

I'd have to pull it up. I don't -- it was another, 10:11:29
you know, related to tobacco smoking or something 10:11:32
else. It wasn't about passive smoking, as I recall. 10:11:34
Q. Is that something that's contained in 10:11:37
Exhibit 564? Could it be -- 10:11:39
A. Yes, it's 5000053. 10:11:50
Q. Let's see what that is. That looks to be a 10:11:50
continuation, actually, of an e-mail that starts on 10:11:56
page 50. 10:12:01
A. Uh-huh.
Q. Do you see that? Is that all one e-mail? 10:12:03
This is 1, 2 and actually looks like we're missing a 10:12:06
page 3 at the top. 10:12:12
A. I'm not sure. 10:12:15
Q. And I don't know whether that was my 10:12:15
copying it or -- 10:12:17
A. Let me see. 10:12:19
Q. -- what I got from you. 10:12:20
A. Yeah. No, I do not have a page 3 either. 10:12:21
Yeah, this -- if you look at 50, the issue that he 10:12:35

cautioned me about was the addiction issue, which I thought was of some interest, but is different from that of the passive smoke. And he asked me not to mix the two in the future. 10:12:37 10:12:41 10:12:44 10:12:48

MR. CAFFERTY: Do you happen to have a page 3? 10:12:53 10:12:55

MS. FROSTROM: What's the Bates number on the bottom of the page? If I have one -- 10:12:55 10:12:56

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MR. CAFFERTY: All right.

MS. FROSTROM: -- I'll be happy to share it. 10:12:57

MR. CAFFERTY: It would be 52. 10:13:00

MS. FROSTROM: I do have that. I don't know how it was omitted, but I have it here. 10:13:03 10:13:04

MR. CAFFERTY: It might have been me in copying it. It may not have been you in providing it. 10:13:06 10:13:07 10:13:09

MS. FROSTROM: Okay. Do you want to look at it now, or do you want me to copy it and give it to you later? 10:13:10 10:13:11 10:13:11

MR. CAFFERTY: Why don't we -- why don't we copy it at the break, and then we'll put it in. 10:13:12 10:13:14

MS. FROSTROM: Okay.

MR. CAFFERTY: Thank you. 10:13:15

THE WITNESS: Okay.

BY MR. CAFFERTY:

Q. All right. So the e-mail that appears on Bates pages 50 through 5 -- I guess it's through 55, it looks like it's six pages. Is that right -- 10:13:16 10:13:19 10:13:29

A. Uh-huh.

Q. -- Dr. Hovell? 10:13:32

A. Uh-huh. 10:13:32

Q. That's the e-mail that Mr. McGuire told you not to send any more like that? 10:13:33 10:13:36

A. Well, he told me not to send content that was outside of the range of this case in one that was also about this case. So I -- I have not sent 10:13:37 10:13:39 10:13:45

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another one since then, so it hasn't even arisen, but -- 10:13:50 10:13:54

Q. All right. What was your purpose in sending this e-mail, the one that's on Bates pages 50 to 56 -- 10:13:54 10:13:56 10:13:58

A. This was primarily --

Q. -- or 55, excuse me. 10:13:59

A. This was primarily to make sure that -- let me see if I'm remembering this. Yeah, this was -- my primary purpose was to check the communications that we had had. Let's see. No. It's the next one that's on 53, is where I was checking the communications we had during the meeting. And then the one that's dated -- or that's numbered 50, is the one where I was providing with additional information. 10:14:01 10:14:05 10:14:21 10:14:24 10:14:29 10:14:33 10:14:35 10:14:39 10:14:42

Q. Why were you providing information regarding addiction? 10:14:43 10:14:49

A. Because I thought he might be interested in it. And that's what he was cautioning me to keep segregated from the information that would be pertinent just to this case. 10:14:51 10:14:53 10:14:55 10:14:57

Q. Why did you believe he might be interested in it? 10:14:58 10:15:00

A. Because he was concerned with tobacco as a 10:15:01

generic. 10:15:03
Q. All right. Let's go back to your notes, 10:15:03
which are page -- 10:15:05

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A. Uh-huh.
Q. -- Bates stamped page 49. 10:15:08
A. 49, uh-huh.
Q. Number 2 I believe says, "What have I then 10:15:11
asked?" What does that mean? 10:15:13
A. I think he started out by asking me what I 10:15:18
had been asked to do, and I then told him that I 10:15:20
thought I was supposed to be responding to the 10:15:24
epidemiology of the literature. And if I recall 10:15:26
correctly, he confirmed that in the conversation that 10:15:30
ensued. 10:15:32
Q. Okay. And then the third entry, what does 10:15:36
that say? 10:15:40
A. This relates to my basic instructions in 10:15:44
the law, which I don't think I passed because I don't 10:15:49
remember it all. But this -- my notes read something 10:15:52
like, "Complaint under California law is unfair and 10:15:53
fraud to sell cigarettes because they are dangerous 10:15:57
and sold to addicts." I think "sold to addicts." 10:16:02
And I believe this was part of the discussion of the 10:16:07
legal foundation for this case. Frankly, I didn't 10:16:11
get involved in that -- in the discussion very much 10:16:15
because I tend to stay with the research that I think 10:16:18
I know. 10:16:22
Q. Is -- is this what Mr. McGuire told you the 10:16:23
case was about? 10:16:25
A. Correct. 10:16:27
Q. All right. Now, I see that it says 10:16:27

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"dangerous and sold to addicts." Is that why you 10:16:29
were sending him information regarding addiction? 10:16:31
A. It may have had some influence on that. I 10:16:33
didn't remember that at the time that I did this. 10:16:35
Q. What's your understanding as to what he 10:16:38
meant about "sold to addicts"? 10:16:40
A. That individuals who buy cigarettes are 10:16:42
likely to be addicted. But that's an inference on my 10:16:45
part he didn't say that. 10:16:48
Q. Do you agree that people who buy cigarettes 10:16:50
are likely to be addicted? 10:16:52
A. In the main. 10:16:54
Q. What do you mean by "in the main"? 10:16:55
A. Sometimes people buy cigarettes for third 10:16:57
parties or second parties. 10:17:00
Q. Do you believe that smokers buy cigarettes 10:17:02
because they're addicted? 10:17:05
A. Yes. 10:17:07
Q. Now, the fourth category, what does that 10:17:10
say? 10:17:13
A. "Don't expose. Don't stand for it." 10:17:13
Q. What does that mean? 10:17:16
A. I can't remember the conversation on that 10:17:20
now very well. I'm sorry, I'm -- I'm not sure. It 10:17:22
probably had something to do with the ETS exposure, 10:17:30
and maybe some of the -- the foundation for this 10:17:33
case. But I -- the legal foundation of the case. 10:17:35
But I don't remember. 10:17:37

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Q. Was that something that Mr. McGuire told 10:17:38

you, or was that something that was your own opinion? 10:17:41
A. It is not my opinion, but it may not be 10:17:48
what he said. It may be some inference I made from 10:17:48
what he was saying. 10:17:51
Q. What are you referring to in terms -- what 10:17:52
do your notes refer to in terms of "don't expose." 10:17:55
Don't expose to what? 10:17:58
A. I assume that means don't expose to ETS. 10:17:59
And it may have to do with the previous where if it's 10:18:03
dangerous -- if cigarette smoking and its exposure 10:18:07
can be dangerous, then it should not be allowed. But 10:18:13
this may be my -- my "don't stand for it" may be my 10:18:16
incidental thought pattern at the time of the 10:18:20
meeting. So I can't recall. 10:18:24
Q. What does that refer to, "Don't stand for 10:18:24
it." Don't stand for what? 10:18:27
A. Exposure, I assume. 10:18:28
Q. And who shouldn't stand for it? 10:18:28
A. Anybody that may be a nonsmoker. 10:18:31
Q. Whether they're exposed to ETS or not? 10:18:33
A. Uh-huh, right. 10:18:36
MS. FROSTROM: Try not to speculate. 10:18:39
THE WITNESS: Okay. 10:18:41
BY MR. CAFFERTY: 10:18:41
Q. And I agree with that, I don't want you to 10:18:42
guess or speculate. But these are your notes, so I 10:18:44
want to understand what you meant -- 10:18:47

A. Understood.
Q. -- when you wrote these things. This is 10:18:48
your handwriting, correct? 10:18:49
A. Uh-huh. 10:18:52
Q. And you did write these notes -- 10:18:52
A. I wrote these out -- 10:18:53
Q. -- at or about -- let me finish, okay? 10:18:53
A. Uh-huh.
Q. And you did write these notes at or about 10:18:56
the time this meeting occurred, correct? 10:18:59
A. Correct. 10:19:00
Q. So that's all I'm trying to do, is just 10:19:01
understand what it is that you meant when you wrote 10:19:03
the words that are on this page. 10:19:05
A. Okay. 10:19:08
Q. Okay. All right. Now, to the left of that 10:19:08
it says, "Dr. Witschi deposition, pages 327 to 330," 10:19:09
what does that mean? 10:19:13
A. I can't remember, but I suppose -- I think 10:19:14
he asked me to look at that. 10:19:17
Q. Do you know who Dr. Witschi is? 10:19:19
A. I know he is another expert witness. 10:19:21
Q. Have you ever met him? 10:19:23
A. No. 10:19:24
Q. Have you ever met any of the expert 10:19:24
witnesses that plaintiffs have named in this case? 10:19:27
A. No. 10:19:30
Q. Number 6, what does that say? 10:19:33

A. "Unethical to create distorted science." 10:19:35
Q. What does that mean? 10:19:38
A. That has to do with my conversation where 10:19:40
Dr. -- or Mr. McGuire was asking me about how I 10:19:45
approach the research methods process, how I view the 10:19:50
scientific method business. And what I was trying to 10:19:53

explain here is that the science is not just a procedure that's used in one study. It's also an entire package of procedures that includes such things as peer review process, and the handling of protection of human subjects that may be in the research, to make sure that they are handled in a ethical and safe way. And that it is also critical to present the science in a way that gives information as to how it was conducted, and welcomes criticism. That it would be unethical to present the science either in an incomplete fashion or to mislead somebody with the information when it's conducted in the science. And this was probably a note that I put down in relation to that conversation, where I was explaining to him how I viewed the entire sequence of events that define scientific method. 10:19:56 10:20:02 10:20:05 10:20:07 10:20:14 10:20:17 10:20:20 10:20:23 10:20:26 10:20:30 10:20:33 10:20:37 10:20:42 10:20:44 10:20:46 10:20:50

Q. All right. Does that refer -- does that statement "unethical to create distorted science" refer to anything related to ETS? 10:20:55 10:20:57 10:21:00

A. No. It would be general in the scientific procedures. 10:21:02 10:21:04

Q. What, in your opinion, would constitute distorted science? 10:21:05 10:21:07

A. Probably the number one would be where you have incomplete information in a research article, or a collection of articles. That's a liability that can occur either by design, that is, somebody is actually not trying to -- to withhold information by design, or it can occur by accident. And the latter is rather common. 10:21:09 10:21:11 10:21:17 10:21:20 10:21:23 10:21:27 10:21:30

Q. Is there anything else, in your opinion, that constitutes distorted science? 10:21:38 10:21:39

A. Well, sure. Straight out fraud would also be. If somebody simply makes up information, or miss -- you know, changes data. 10:21:40 10:21:43 10:21:46

Q. Anything else? 10:21:49

A. That's all that occurs to me right now. 10:21:52

Q. Have you ever seen any studies involving ETS that have represented distorted science because there's been incomplete evidence? 10:21:54 10:21:57 10:22:00

A. I think most of the studies I've reviewed could be subject to criticism for incomplete reports, but that's not unique to ETS. 10:22:02 10:22:04 10:22:09

Q. So would it be fair to say that the studies that you've reviewed that are incomplete represent distorted science? 10:22:11 10:22:15 10:22:19

A. The -- 10:22:21

MS. FROSTROM: Objection; argumentative. 10:22:21

THE WITNESS: The degree to which they are incomplete raises questions that may not be answerable by reading the report of the science. 10:22:24 10:22:25 10:22:29

BY MR. CAFFERTY:

Q. Could you tell me, as you sit here today, which reports regarding ETS you've reviewed that have contained incomplete reports? 10:22:31 10:22:35 10:22:40

A. All of them in some sense. For example, if there's inadequate information on the sample, or how it was selected, or inadequate information on the measurements employed, then I would consider those incomplete. There's a distinction here between they didn't do it, or didn't do it correctly, versus 10:22:44 10:22:48 10:22:51 10:22:54 10:22:56 10:23:01

didn't tell me how they did it. And both are important. 10:23:02 10:23:05

Q. Okay. How about your own reports, have your own reports always been complete? 10:23:14 10:23:14

A. No. 10:23:14

Q. Does that mean that your reports have been distorted science? 10:23:16 10:23:17

A. They run the risk of being distorted. I would like to -- I believe they were not fraudulent. I believe they were fair and honest. But the process of publishing papers results in a compromise between providing sufficient detail and writing the paper in such a way that it meets page limitations of the journal. So there are -- there are compromises that occur that are a function of cost rather than good science procedure. 10:23:18 10:23:20 10:23:24 10:23:27 10:23:32 10:23:36 10:23:39 10:23:41 10:23:43

Q. Have you any -- have you ever seen any ETS literature that you believed represented distorted science because it was fraudulent? 10:23:44 10:23:46 10:23:50

A. I have serious doubts about the -- I am not a student of the authors of all of this literature, but in some cases I have serious doubts about any study that is primarily funded by a proprietary interest. 10:23:56 10:24:01 10:24:04 10:24:07 10:24:11

Q. What do you mean by that? 10:24:11

A. If the agency paying for the science also has a benefit to be gained by the outcome of the science, it raises questions about the objective nature of the science. 10:24:12 10:24:15 10:24:18 10:24:21

Q. In the ETS context, what does that mean? 10:24:22

A. That means if a tobacco industry funded studies in that area, I would raise questions about its objectivity. 10:24:26 10:24:27 10:24:30

Q. What questions would you raise? 10:24:32

A. Whether or not it was completely honest. 10:24:34

Q. Okay. Number 5, we kind of skipped -- 10:24:38

A. Yes.

Q. -- over that one, I'm sorry. I missed that one. What does that say? 10:24:43 10:24:44

A. "No outcome versus no harm." 10:24:45

Q. What does that mean? 10:24:50

A. The "no" -- this was part of a conversation where I -- I was trying to explain my view of the scientific methods again. And in that process you could view a continuum from, at the worst case, some 10:24:52 10:24:54 10:25:01 10:25:06

service, some agent, something like tobacco or a drug or whatever might cause harm at one end of the continuum. It might do absolutely nothing, neither harm nor benefit. Or at the other end of the continuum it might actually provide benefit. 10:25:10 10:25:14 10:25:18 10:25:21 10:25:24

In research designs, ordinarily they are structured to test whether or not there's a difference from no outcomes, meaning doing neither harm nor benefit, to either producing a harm or benefit. Sometimes assessing both harm and benefit. Occasionally studies are designed to compare the null outcome, meaning having no effect in a sense, to a defined harm or defined benefit. One direction only examination. 10:25:26 10:25:30 10:25:32 10:25:37 10:25:41 10:25:46 10:25:50 10:25:56 10:25:59

In this instance the null outcome is a very special concept in that it does not mean that we know 10:26:00 10:26:04

that something is either harmful or beneficial, or 10:26:08
that it is not harmful or is not beneficial, rather 10:26:12
it just means we don't know. So the way you could 10:26:17
view null outcome is as if the study had not been 10:26:19
done. 10:26:23
THE VIDEOGRAPHER: Your head is getting in 10:26:31
the way. Sorry. 10:26:32
THE WITNESS: The art of photography. 10:26:33
At any rate, this -- this note here, I 10:26:35
presume, I can't remember the exact conversation, was 10:26:37
to indicate that if one has a study and finds, let's 10:26:39
say, a nonsignificant outcome, you might conclude 10:26:43

that that means that it was a null outcome, meaning 10:26:46
technically may have been no different from that of 10:26:50
no effect at all. That's not the same logically as 10:26:54
saying that it is free of harm. It's -- it's closer 10:26:58
in analogy to saying that we aren't sure what the 10:27:01
results are. So that was the point of this note, I 10:27:04
believe. I can't remember for sure. 10:27:09
BY MR. CAFFERTY:
Q. All right. How does that -- how do those 10:27:10
principles apply in the context of ETS? 10:27:13
A. In the case of ETS, it would be possible to 10:27:16
design a study to look for both harm and benefit. 10:27:19
And if you did, you would normally contrast any 10:27:24
difference that would indicate either a harm or a 10:27:27
benefit against a no difference and no effect, which 10:27:29
would be the null outcome. Actually, my reading of 10:27:35
the literature shows that it is predominantly looking 10:27:37
at the possibility of harm. I see very little 10:27:40
research that has been directed to identifying 10:27:43
possible benefits of passive smoke exposure. 10:27:44
Q. What kind of benefits would you expect 10:27:48
there to be of passive smoke exposure? 10:27:49
A. Actually, I don't -- I don't think there 10:27:54
are any. I'm personally unaware of benefits from 10:27:55
passive smoke exposure. 10:27:58
Q. Not aware of any at all? 10:28:01
A. Huh-uh.
Q. Okay. How would you design a study to look 10:28:03

at the harm and the benefits of passive smoke 10:28:06
exposure? 10:28:07
A. That's a very large question. It's not 10:28:10
subject to an easy and simple answer. It's, first of 10:28:13
all, not one study. It's a series of studies. Some 10:28:15
of which are in the literature and some of it -- some 10:28:19
of which have not yet been done. 10:28:21
But, ideally, you would build in an 10:28:23
incremental fashion. You would start with -- not 10:28:25
unlike the literature has, with case control designs, 10:28:29
which is an efficient study design to see if there's 10:28:31
an association between ETS exposure and some kind of 10:28:33
outcome, either a benefit or a harm. You would move 10:28:42
from that, perhaps, to longitudinal designs, and 10:28:42
there are a few of those in the literature. And then 10:28:46
in a theoretical sense you would move closer and 10:28:47
closer to quasi-experimental or fully -- what's 10:28:51
sometimes referred to as fully controlled 10:28:55
experimental studies. 10:28:56
The difficulty with experiments in tobacco 10:28:58
research is that it's generally considered unethical. 10:29:00

Such an experiment in general would require that we take nonsmoking or nonexposed people and ask them to be exposed to tobacco for one group and not for another, and then follow them for an extended period of time, perhaps 10 to 30 years, to see what the health outcomes were. The feasibility of that study would be very difficult. The ethics of the study 10:29:05 10:29:07 10:29:12 10:29:15 10:29:17 10:29:20 10:29:23

would probably preclude it from being doing -- being done at all. The longitudinal studies that might -- some of which have been done, but are very difficult to do. And, say, nested case control designs that are sort of a next level up from a straight longitudinal study are extraordinarily expensive and very difficult to do well. And have yet to be done, so far as I'm currently aware. 10:29:26 10:29:28 10:29:33 10:29:35 10:29:38 10:29:41 10:29:46 10:29:48

So in that continuum you could imagine doing a series of studies that would increase in the quality of the science procedures being used on a whole host of -- 10:29:51 10:29:53 10:30:04

THE REPORTER: I'm sorry. That would increase what?

THE WITNESS: In the quality of the science being employed over a very host, or large range, of procedures, everything from measurement to research design structure. 10:30:05 10:30:08 10:30:13

It's possible now, in my judgment, to do certain limited experiments, either short-term exposures -- and there are a few of those that have been done with people. I have not read them all, but I've seen one or two. And it's also possible to do studies of the discontinuation of exposure. Although those are also very difficult, and feasibility can be questionable. And, to my knowledge, there are none like that in the literature, large-scale experiments where exposure has been discontinued to see if there 10:30:16 10:30:19 10:30:22 10:30:25 10:30:27 10:30:31 10:30:34 10:30:38 10:30:45 10:30:46

was a reversal in possible outcomes, either benefits or ill health. 10:30:50 10:30:55

BY MR. CAFFERTY:

Q. Would you consider a study regarding ETS funded by an antismoking group to be something that you would have concerns about whether or not it was objectively performed? 10:30:58 10:31:02 10:31:06 10:31:09

A. Absolutely. 10:31:11

Q. Let's jump to Number 7, because it seems to have some relationship to Number 5 that we were just talking about. What does that say? 10:31:18 10:31:21 10:31:24

A. "Never offered to study" -- I think that's "offered," but I'm not -- I'm not sure -- "proving the null outcome." 10:31:26 10:31:29 10:31:32

Q. What does that mean? 10:31:35

A. I'm not sure what my note is. It's not good English, at the very least. But the issue that I think I was discussing is that in logic, in the scientific logic, it's not possible to prove a null outcome, so failing to find a significant study finding. So at some probability standard, such as the classic alpha level of P05, if a study fails to reach significance, then what we know is it has not demonstrated an effect. But that is not the equivalent of saying it has no effect. We have no information of no effect, so the null outcome can't 10:31:37 10:31:40 10:31:43 10:31:45 10:31:49 10:31:54 10:31:57 10:32:04 10:32:07 10:32:10 10:32:12

actually be proved. You can't prove the absence of something. 10:32:16 10:32:19

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Q. You can't prove a negative? 10:32:19
A. Correct.
Q. Okay.
A. You can produce -- you can prove an ill outcome, such as an illness. You can prove a benefit outcome in some sense. Although even the word "proof" there is technically a bit overstated. But you can't a null outcome. 10:32:21 10:32:25 10:32:28 10:32:31 10:32:34
Q. What did you mean by "alpha level P05"? 10:32:36
A. The alpha level is the standard that's generally used in science to declare that an association in any kind of a research study has reached a level of statistical significance that is generally believed to rule out chance findings. So if something is, quote, significant, at a probability level of P05, 5 in 100, then that -- that says the probability of observing what we've seen in this study is only 5 in 100 likely to be due to chance. 10:32:40 10:32:42 10:32:46 10:32:50 10:32:55 10:32:59 10:33:02 10:33:08 10:33:10
Q. Okay. And what is the significance of the P05 level? Is that a standard level that's used? 10:33:15 10:33:17
A. It's a traditional level that's used. Actually that's a good question, in that it's a somewhat arbitrary level. It could be set at a higher or lower level, and there are a number of conditions that might go into a decision to set it at a higher or a lower level. But most commonly it's set at a "P" of 05, with a two-tailed test. And what that -- what that generally means is that you are 10:33:21 10:33:23 10:33:25 10:33:29 10:33:32 10:33:34 10:33:41 10:33:45

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going to treat as an -- a highly likely truthful event, or correct observation, any observation where the association observed meets the statistical test of significance at a "P" of .05. 10:33:46 10:33:53 10:33:56 10:34:00
Q. What did you mean by the fact that -- or by your -- your statement that it's the traditional level that's used? 10:34:10 10:34:10 10:34:10
A. Well, it's commonly done. And in some instances it's arguable as to whether the "P" value actually set for a particular study is necessarily the correct one. For example, if you use a "P" of probability of 05 on a two-tailed test, and the study that you're doing may have extreme risks, for example, a surgical study, where somebody might die in the course of surgery, it would be common, and, perhaps arguably very wise, to not limit your declaration that this surgical procedure is an effective procedure if it were significant only at the "P" of 05. You might want to move it to a "P" of 01, or even more stringent, so that you could rule out the possibility of recommending a procedure for routine use that might be dangerous occasionally. 10:34:10 10:34:13 10:34:16 10:34:18 10:34:23 10:34:30 10:34:35 10:34:39 10:34:43 10:34:47 10:34:51 10:34:54 10:34:58 10:35:02 10:35:05
So if, for example, your study found that it looked like the surgery was efficacious and may help people, repair an illness, save their lives, but it did so with an occasional person dying in the course of surgery, that would be a very unfortunate outcome if it turned out that the observation of 10:35:08 10:35:09 10:35:13 10:35:17 10:35:20 10:35:23

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benefit was wrong. And all studies run the risk of being wrong, even if they reach significance. 10:35:26 10:35:29

Conversely, if you had a study which was looking at harm, such as a drug test that might be going through FDA approval, and you had reason to suspect that, say, treating a drug -- a drug that's used for treating cholesterol might also cause illness, then we may want to -- and your study is designed to test for the illness, the ill effects, then you may want to relax the alpha standard, because the standard there is one of being conservative. If it is possibly causing ill health, and if there are other drugs that could be used that are safer, then a policy decision might be used to restrict it. In that case then a "P" of maybe .1 would be preferable to "P" of 05, or more stringent. 10:35:33 10:35:35 10:35:39 10:35:42 10:35:45 10:35:49 10:35:52 10:35:56 10:35:59 10:36:00 10:36:04 10:36:06 10:36:09 10:36:14

There are other conditions that also play in that decision if the expected direction of an intervention's effect is only one direction. So if you expect a drug, for example, to have only a beneficial effect, and there's no theoretical or empirical reason to believe that that drug would have a harmful effect, then it may be legitimate to construct a study where you're using the probability of 05, but that would be for a one-tail test. And that's the equivalent of a probability of .1 for a two-tailed test. So it would be the equivalent of a somewhat relaxed standard, because you're looking in one direction rather than both. 10:36:18 10:36:20 10:36:26 10:36:29 10:36:32 10:36:36 10:36:38 10:36:43 10:36:45 10:36:50 10:36:54 10:37:00

10:37:03

The question is actually a little different. You're asking, "Does this drug cause benefit versus either no effect or harm?" Because you only expect it to cause benefit, you're looking at that one end of the continuum versus all else. That's contrasted with two-tailed tests where the technical question is, "Does this drug cause any effect versus no effect?" And the effect could either be benefit or harm. 10:37:06 10:37:07 10:37:09 10:37:15 10:37:18 10:37:21 10:37:24 10:37:27 10:37:29

Q. Why don't we come back to that thought and take a break first. I think we've been at it for a while. 10:37:33 10:37:36 10:37:39

A. Sure. 10:37:40

Q. And we'll pick up with that when we come back. 10:37:40 10:37:42

THE VIDEOGRAPHER: This concludes Tape 1 of the videotape deposition of Dr. Melbourne Hovell. Off the record at 10:37 a.m. 10:37:43 10:37:45 10:37:49

(Recess taken.) 10:53:01

THE VIDEOGRAPHER: This is Tape 2 of the videotape deposition of Dr. Melbourne Hovell. Back on the record at 10:52 a.m. 10:53:34 10:53:36 10:53:39

BY MR. CAFFERTY: 10:53:44

Q. All right. Dr. Hovell, before we took our break we were talking a little bit about one-tailed and two-tailed tests. Could you just tell me in simple terms what the difference is between a one-tailed test and a two-tailed test. 10:53:45 10:53:48 10:53:51 10:53:54

10:53:56

A. The primary difference is the way the question being asked in the science is structured. In a one-tailed test, you're asking a directional question. Does something cause benefit, does something cause harm. And it either does or it doesn't in a dichotomous sort of outcome. So if it 10:53:59 10:54:00 10:54:05 10:54:08 10:54:11 10:54:16

causes benefit, that says contrasted with either having no effect or harmful effect combined. 10:54:20 10:54:24

And in the case of a two-tailed test, the question is structured differently. It is structured as, "Does the effect cause either harm or benefit?" Does it have any effect other than a null effect. 10:54:27 10:54:29 10:54:32 10:54:39

Q. What difference does that make to the statistical analysis in a people epidemiology study? 10:54:48 10:54:51

A. Well, it may not make any difference, depending on how it's set up. It doesn't have to make a difference. But in many studies the question being addressed may be directional, and yet the investigator may have adopted a "P" value that would normally be adopted for a two-tailed test. If that were to happen, it would be a more conservative test than might be arguably necessary. 10:54:56 10:54:59 10:55:01 10:55:04 10:55:14 10:55:14 10:55:17 10:55:20

So, for example, a two-tailed test at a probability of .05 is the equivalent of a one-tailed test at a probability of .1. So if one were doing a one-tail question, that is a directional question, but used a probability or alpha setting of .05, then 10:55:22 10:55:27 10:55:31 10:55:36 10:55:40

it would either be that you were interested in being even more conservative in the study design, or arguably you were using too conservative an alpha level, and it should have been a .1. 10:55:45 10:55:46 10:55:51 10:55:56

And the reason I mentioned earlier that it's tradition to use a .05, and sometimes that is even when it's a single-tailed test in principle, is because we're sometimes surprised. And even when we thought that there was only a directional outcome, there may have been a bi-directional outcome. And so to be conservative, some people will always use a two-tailed test design. But that's -- that -- that is a debatable part of the design. And it is debated on the basis of both theory, as well as the empirical evidence to date, when the study is being designed. 10:55:58 10:55:59 10:56:04 10:56:07 10:56:10 10:56:12 10:56:17 10:56:20 10:56:23 10:56:27 10:56:32

Q. Have the people ETS epidemiology tests traditionally been one-tailed or two-tailed tests? 10:56:34 10:56:38

A. My observation so far is that they have been two-tailed tests. With some exceptions, I believe in some of the meta-analyses and possibly, although I couldn't point to it, in the Cal EPA report, where there may have been some one-tailed logic employed. 10:56:42 10:56:43 10:56:48 10:56:51 10:56:54 10:56:57

Q. Do you have further review that you have to do to answer that question fully? 10:56:59 10:56:59

A. If it's critical, I can do that review; and yes, I would have to do the review to find it, because, I mean, it's an incidental event. And from 10:57:02 10:57:03 10:57:06

my point of view, if you have a large body of evidence that tends to point almost exclusively in one direction, then the next line of studies to be conducted might be justifiably a one-tail question. And in that case the alpha level would be set accordingly. That may be a less conservative approach to design than if one were to continuously or repeatedly use a two-tailed test design, even after mounting evidence that it appears to be a one-directional event. 10:57:10 10:57:13 10:57:16 10:57:19 10:57:23 10:57:26 10:57:32 10:57:35 10:57:38 10:57:42

Q. Have the people ETS epidemiology studies traditionally used a "P" equals .05 value? 10:57:45 10:57:50

A. I believe so, in my readings to date. I don't recall seeing one that was different. 10:57:54 10:57:57
Q. Let's go to Number 8 on page Bates Number 49 of -- 10:58:06 10:58:13
A. Uh-huh.
Q. -- Exhibit 564. And 8 is -- I think it's an 8. It's between 7 and 9, at least. It looks sort of like an 8. Is that an 8? 10:58:14 10:58:17 10:58:21
A. It is an 8. It is a bad 8, but -- 10:58:23
Q. What does that say? 10:58:26
A. "Explain defining minimum size a priori, and then design the study to detect this size effect." I believe in the parentheses it says "(null study)," but I'm -- I'm not sure. 10:58:28 10:58:32 10:58:38 10:58:40
Q. All right. What does that mean? 10:58:42
A. I believe at this point I was talking with 10:58:44

Mr. McGuire about the importance of setting at the beginning of a study design the size of effect, and in this case that means the size of an association that you're trying to identify. You may set it within a range, but you would normally identify the size of an effect that you hope to be able to find. And then you design your study so that it has sufficient power, which is a technical term, a statistical power, to identify that size effect or larger. 10:58:47 10:58:52 10:58:56 10:58:58 10:59:02 10:59:05 10:59:10 10:59:12 10:59:14 10:59:17
So, if I could give an analogy, if you were looking through a microscope and you wanted to identify mold in a petri dish, you might use a relatively modest lens. On the other hand, if you were looking for a much smaller organism, say a bacterium or a virus, then you would have to move to a much more powerful microscope to find so small an animal. So the research design should follow accordingly. If you're going to be looking for a relatively big thing, big association, then the power need not be so great to find it. If you're looking for a relatively small effect, then the power needs to be greater. 10:59:18 10:59:25 10:59:27 10:59:30 10:59:36 10:59:40 10:59:44 10:59:49 10:59:50 10:59:52 10:59:55 11:00:01 11:00:05
If we -- if one were to know in advance and have theory or previous research that strongly suggests, at least in broad strokes, the probable size of most associations, that might be true for, say, ETS and some kind of ill health outcome. You 11:00:06 11:00:11 11:00:15 11:00:19 11:00:22

might look at that literature and say, "This looks like a small to moderate effect. It is not a big effect." Sometimes in the literature that's been contrasted with the kinds of ill health effects that are sometimes reported for tobacco smoking, and by contrast it's a relatively small effect. 11:00:26 11:00:29 11:00:33 11:00:41 11:00:41 11:00:45
If you think it's a relatively small effect, then you are -- by obligation you should be designing your next study to have sufficient power to identify a small effect or larger. If you were to design the study without sufficient power, then that would either be very naive research, or it could even be misleading the literature, because you've structured a study that at its outset could not answer the question. 11:00:48 11:00:50 11:00:53 11:00:57 11:01:03 11:01:05 11:01:10 11:01:12 11:01:15
So in the design of the study, one of the first things one would normally do is set the effect 11:01:16 11:01:19

size that you hope to be able to detect, and then design the study in such a way that you're pretty sure you could detect that size or larger. 11:01:25 11:01:29 11:01:30

Q. What's the lowest effect -- and when you say "effect size," what do you mean by effect size? 11:01:35 11:01:36

A. The size of the association that's presumed to exist, if one exists at all. 11:01:38 11:01:41

Q. How do you -- how do you define the size of the association? Is there a term for that? 11:01:43 11:01:46

A. There are many -- there are many different ways to do that. The ones that are commonly used in 11:01:48 11:01:50

the ETS literature would be -- especially with case control, and either epi studies would be a relative risk ratio or an odds ratio, which is an estimate of a relative risk ratio. It's a comparison of the risk rates in the exposed condition, or group, to the risk rates in a comparison or unexposed group. So if the relative risk is a 1, it means they are equivalent. And that's also the equivalent of no association. So a relative risk greater than 1 would imply that one group is at much greater risk than the other. And a relative risk less than 1 would imply that one group is at less risk than the other. Depending on how you set up the comparisons, it would -- it would define the direction. 11:01:52 11:01:55 11:02:01 11:02:04 11:02:11 11:02:14 11:02:18 11:02:21 11:02:24 11:02:29 11:02:33 11:02:37 11:02:40 11:02:43

So, in this instance, my reading of the literature for I believe lung and I also believe for cardiovascular disease, has often been reported with odds, or relative risk ratios, of approximately 1.2 to 1.3, where that means there's approximately a 20 to 30 percent higher risk for people exposed to passive smoke compared to people that are presumed to be not exposed to passive smoke. That's a relatively small effect in the overall research design process where you might see relative risks well in advance of 2, 2.0. So if you have other evidence that the risk ratios are falling in this lower end of the continuum, then any new study that should be done, say, from today forward, should take that into 11:02:46 11:02:48 11:02:52 11:02:58 11:03:00 11:03:05 11:03:08 11:03:12 11:03:17 11:03:23 11:03:27 11:03:31 11:03:34 11:03:38

consideration, and you should be designing the study in a way that would honestly give you a very good chance of finding a risk ratio of, say, 1.2. 11:03:40 11:03:44 11:03:47

If you designed it so that it could only find a risk ratio of 1.5, then it would almost be unnecessary to do the study. It would be insufficiently powerful enough to find the likely -- the observed ratios of, say, 1.3. And then you might end up concluding that there was no association, when, in fact, what you should conclude is that you didn't have enough power to answer the question. 11:03:52 11:03:55 11:03:59 11:04:02 11:04:04 11:04:08 11:04:11 11:04:14

Q. Have some of the ETS studies performed to date not been honestly defined to capture the small relative risks that you'd expect to see? 11:04:16 11:04:18 11:04:25

A. I can't speak to their honesty, but I can speak to my impression. When I read some of the literature, some of the case control studies have relatively small samples. And the sample size is one of the variables that impinges or influences the power of the study. It's not the only one, but it is one of them. And if the sample size is too small at the outset, then it is highly unlikely to find a 11:04:27 11:04:31 11:04:33 11:04:34 11:04:37 11:04:41 11:04:44 11:04:47

significant association. And that could lead to a conclusion that there's no effect, when, in fact, the better conclusion would be that we haven't designed the study with sufficient power to determine an effect. 11:04:53 11:04:57 11:05:00 11:05:04 11:05:06

Q. Which studies that you reviewed fall in that category? 11:05:08 11:05:10

A. In some sense most of them. And I'm not good at reporting on specific studies, unless I pulled them out and studied them with you, but -- but -- and that could be done. But let me give you an illustration. 11:05:12 11:05:16 11:05:18 11:05:20 11:05:23

There's two levels of analysis that often occur in many studies. The first is a overall comparison of a case group and a control group. Usually that's done with roughly the -- the number of people that were originally planned for the study. However, it's often also possible to, for example, stratify by gender and compare the subset of people who are men in the case in control group or women in the case in control group. And as soon as the studies begin looking at subsets of the original sample size, they begin to move into smaller and smaller subset -- sample sizes for the smaller subset of the overall paper. In many instances I question whether those sample sizes are sufficient to answer the question with adequate power. 11:05:23 11:05:25 11:05:29 11:05:32 11:05:35 11:05:44 11:05:44 11:05:47 11:05:49 11:05:51 11:05:54 11:05:59 11:06:03 11:06:05 11:06:08

I've also seen, in most of the studies I've read, very little -- and I don't think I've seen a study yet that has an explicit power computation in the report. It is possible to compute the power. And in a null outcome study, arguably, that would be very important. If a -- if a study failed to find significance, say the "P" value achieved was in the neighborhood of a .2 instead of a .05, the logic gets a little bit tenuous here, but it's possible that it's just chance, and there is no association operating. It's also possible that had they had a larger sample size, or possibly more refined measures in other ways, that that study could be repeated with sufficient power that the same effect observed would now be statistically significant. 11:06:11 11:06:15 11:06:18 11:06:22 11:06:25 11:06:28 11:06:30

11:06:36 11:06:40 11:06:45 11:06:47 11:06:51 11:06:56 11:06:58 11:07:03

The difficulty in that, and the reason it's so important to replicate studies like that, is that the sample employed in the initial observation may not be representative of a new and larger sample. So the replication remains critical. But the decision to replicate may be made in part on how near -- how close to a significant finding might we have been. So, for example, if we found an association was significant at the .2 alpha level instead of the standard .05, and we computed the power for that study and identified it to be, say, in the .6 or lower level, which would be to say you had about a 60 percent chance of finding a significant effect with this size of an association, then that might be encouraging. It might say, "Well, with a somewhat larger sample size we could probably boost our power, and that might be sufficient to detect this outcome," and -- but it would still require replication. If, on the other hand, you had power of point, say 8 or 11:06:56 11:06:58 11:07:03 11:07:06 11:07:08 11:07:12 11:07:15 11:07:18 11:07:22 11:07:26 11:07:29 11:07:36 11:07:38 11:07:42 11:07:46 11:07:50 11:07:51 11:07:55 11:08:00 11:08:01 11:08:05 11:08:10

higher, and you found no significant finding, that would imply that your power was probably satisfactory, and it would contribute to a decision that you have no effect.

Q. I'm having a little trouble understanding what you mean by "power" in --

A. Okay.

Q. -- this context. You just used the number .8 for power. What did that -- what did you mean?

MS. FROSTROM: Let me just interject. I'm not sure how much of the previous answer was responsive to the question, and I would caution the witness to stay within the confines of the question asked.

THE WITNESS: Okay, I'll try.

Answering the second question, "power" is the probability of being able to detect an association of a given size. And it is a statistical concept that is computed based on the sample size based on the size of the association you're trying to identify, based on the measurement error or variance. And if you were to manipulate one of those variables in an algebraic fashion, you can solve for another. And so, for example, if you -- and it's also based on the probability level you set.

So, for example, if you set your alpha level a priori at a two-tailed test of .05, and you have a defined effect size that you wish to discover, or detect, such as an odds ratio of say 1.2 or

larger, and if you have information from previous studies regarding the amount of variance in previous associations that have been observed, you could then estimate the sample size you need to have a power of, say, .8 or .9, which would be the probability of finding an effect of that size, statistically significant.

BY MR. CAFFERTY:

Q. Okay. So the .8 means you have an 80 percent chance of finding an effect at the level --

A. You've set.

Q. -- you've set?

A. With the alpha level that you've set, uh-huh.

Q. All right. Now, what I'm having trouble understanding is, is it your testimony that the ETS studies that have been performed to date have not had sufficient power to identify the small effects that you might see?

A. In some cases, and in some of the subanalyses, yes.

Q. Okay. Does that mean that further work needs to be done to do studies that have sufficient power?

MS. FROSTROM: Incomplete hypothetical, vague and ambiguous.

THE WITNESS: It does mean that further work needs to be done, but it is not limited to that.

Further work needs to be done for a lot of reasons.

BY MR. CAFFERTY:

Q. What are the other reasons?

A. Because all of the studies to date have used a series of research methods that are, as yet, not exhausting the quality of the research that could be imagined. So the nature of the research process is kind of a never-ending process, until we have so much information that we consider a subject really well understood, and then only until somebody comes up and interrupts us with some new observation that causes more science to go forward. So in a theoretical sense, there's no end to the research that's needed. 11:11:03 11:11:06 11:11:09 11:11:16 11:11:16 11:11:21 11:11:23 11:11:26 11:11:30 11:11:32 11:11:35

The studies that have found significant associations stand on their merits, and are -- in all likelihood represent true relationships between passive smoke exposure and ill health. But some of the analyses have failed to corroborate that, and some of those may be due to inadequate power. Some of the subanalyses, say, for women, or for men, or for certain age groups, may also suffer inadequate power. And in those instances they should be replicated with larger samples in order to best answer those questions. 11:11:36 11:11:39 11:11:43 11:11:47 11:11:50 11:11:54 11:11:57 11:12:01 11:12:04 11:12:07 11:12:11

Q. I'm still struggling a little with this. Is it your opinion then that in the ETS epidemiology area that we don't yet have so much information that we consider the subject of ETS in association with disease really well understood? 11:12:18 11:12:23 11:12:29 11:12:37 11:12:42

MS. FROSTROM: Vague and ambiguous, argumentative, incomplete hypothetical. 11:12:45 11:12:45

THE WITNESS: My answer to that would be that we can say with some confidence now that there is an association between passive smoke exposure and a number of different kinds of ill health. That does not mean that there isn't important reason to advance the science to further explore that association and to advance the understanding of the relationship between passive smoking and ill health. 11:12:50 11:12:51 11:12:54 11:12:57 11:13:01 11:13:03 11:13:07 11:13:11

BY MR. CAFFERTY:

Q. What further advancement in the understanding of the relationship between passive smoking and ill health do you think is necessary? 11:13:15 11:13:17 11:13:20

A. My -- I'm going to answer that in two ways. The first is that primarily I'm concerned with the nature of the research methods employed in the overall area of ETS science. So, for example, as many of the published -- publications have mentioned, the quality of the measures employed to assess ETS exposure remains to be refined. We've made great advances in that area, and there are some pretty good measures in the field, but they should be much better. They could be much better. As they improve, it should enhance the quality of the science that would refine the precision of associations that might be discovered. 11:13:25 11:13:29 11:13:34 11:13:36 11:13:41 11:13:44 11:13:48 11:13:56 11:13:58 11:14:00 11:14:04 11:14:06 11:14:10

With regard to design, most of the studies in the literature to date have been case control study designs. A few of them have been perspective or cohort designs. And I think we need more cohort designs. And ideally we should approach perhaps even nested case control designs, which is a case control design nested within a cohort design. And I could 11:14:12 11:14:18 11:14:20 11:14:23 11:14:27 11:14:34 11:14:37

explain that at some length, but it's a more advanced design. Some of the reason for doing that is that it provides more information about the conditions necessary to conclude that there's a causal relationship between, say, ETS exposure and ill health. As we improve the measures, for example, we will have a better understanding of whether exposure was actually taking place or not. In -- in the current literature I think there is okay understanding about crude levels of exposure in many of the exposed groups. So they are living with somebody that smokes, and the presumption is they at least occasionally are exposed. However, there is little in the literature that I've seen so far that convinces me that the controls that are supposed to be unexposed are, in fact, unexposed. We don't know how limited their exposure may be or how extensive, in some instances. That's not reported. And it may not have been measured. It may be presumed by the design. So enhancing the measures would allow us to

structure designs which would give us clearer information about exposure versus nonexposure for the structure.

As we move to perspective studies and do more of them, they would provide an opportunity to make sure that the exposure is coming before the illness. So it gives us information about the logic of temporal order. If somebody has a lung cancer prior to exposure, then it could not be their exposure that actually causes the lung cancer, even though there may be an association. That's not a very likely event, since lung cancer takes a long time to acquire. So even in the case control studies the implicit evidence is strong for temporal order, but it is not explicit. Perspective studies make that explicit. Then there are a host of other design features like that that could be advanced, and should be advanced, in this field.

Q. Why do you think they should be advanced?

A. Because that's the way all science progresses. And it will confirm -- it will do two things. It would either confirm the previously identified associations with greater precision, or, in some unlikely event, it might refute them. In the natural history of an evolution of an area of investigation, it's not without -- you know, I don't know if it's 1 in 10, or whatever, but if you were looking at, say, a medical treatment program that was

promising, it had an incidental observation that looked like a new treatment was going to help people, and you ran a case control design and found a fairly strong association, and subsequently a perspective and maybe experimental study, it wouldn't be unusual to find that the effects were smaller by the time you got to the experimental analysis.

Q. Are you aware of any examples where further research has refuted earlier conclusions that a particular disease was caused by some action?

A. I do not --

MS. FROSTROM: Objection; overbroad.

THE WITNESS: I do not have that

information for a disease association. I do have it for treatment associations. And I've coauthored papers that have looked at the medical literature where a promising procedure, say -- I believe the treatment was a light treatment, incandescent, or maybe ultraviolet light, on mouse ulcers, and it was a promising treatment, which, when tested by control trial designs, did not prove significantly different from a placebo procedure. So, yes is the simple answer. There are conditions where initially identified associations in a case control design do not necessarily hold up when the science is advanced to more rigorous design features. 11:17:56 11:17:59 11:18:03 11:18:05 11:18:12 11:18:18 11:18:21 11:18:25 11:18:28 11:18:33 11:18:35 11:18:37 11:18:40

BY MR. CAFFERTY:

Q. So is that the stage that ETS is at, that you believe it needs to advance to more rigorous design features? 11:18:45 11:18:48 11:18:53

MS. FROSTROM: Objection; argumentative. 11:18:55

THE WITNESS: I think the stage now is somewhere between case control and longitudinal designs. There have been a few longitudinal designs published, and I've read a couple of those. So, in the simple answer, yes, I think there's a lot of room for advancing the rigor of the science. 11:18:56 11:18:58 11:19:01 11:19:04 11:19:08 11:19:09

BY MR. CAFFERTY:

Q. Okay. Let's go back to your -- your notes from the June 23rd conference, and, again, we're back on -- 11:19:11 11:19:15 11:19:19

A. Uh-huh.

Q. -- Bates Number 49 in Exhibit 564. We're up to Number 9. And I can't read that one at all. What does that say? 11:19:19 11:19:24 11:19:27

A. That's supposed to say "Terminology." 11:19:28

Q. Terminology, okay. 11:19:31

A. And I don't remember exactly what this means. I suspect he was asking me to be careful with my terminology. That is, he wanted me to use words he understood. 11:19:32 11:19:34 11:19:36 11:19:40

Q. That's very important for us lawyers in dealing with you scientists. I'd ask that you keep that in mind today. All right. 11:19:41 11:19:44 11:19:49

And then 10 is just the deposition dates, which -- 11:19:51 11:19:52

A. Right. 11:19:53

Q. -- say today and tomorrow? 11:19:53

A. Right. 11:19:55

Q. Which is what we're heading for for your deposition. 11:19:56 11:19:59

Now, 11 says -- I don't know exactly what it says. What does it say? 11:19:59 11:20:01

A. "Two-headed cow high dose." 11:20:03

Q. What -- what does that mean? 11:20:08

A. We should review this when we're ready to end. It's a better ending conversation, but -- I can't remember exactly how this came up in the conversation with Mr. McGuire. But I was trying to describe the logic of, once you have demonstrated an event relatively definitively, then the science precedes to embellishing the frequency of the event, the nature of the event, the details of the event. And the crude and perhaps humorous analogy was, if 11:20:08 11:20:11 11:20:13 11:20:16 11:20:19 11:20:25 11:20:29 11:20:33 11:20:36

you identified one two-headed cow, then we know 11:20:40
two-headed cows can exist. And so now the science 11:20:45
advances to how many two-headed cows might exist, and 11:20:49
what are their nature beyond simply having two heads. 11:20:52
And in this case I think the analogy was to high 11:20:57
dose. So in some of the studies, particularly animal 11:21:00
studies, the nature of the design of an animal study 11:21:03
not limited to ETS research would be to employ a 11:21:06
relatively high dose toxin to see if it produces an 11:21:09
effect at all. If it does, that gives you your 11:21:14

two-headed cow. We now know something can happen. 11:21:16
Now we need to go on to do the studies to 11:21:21
find out what happens at overdose, what happens under 11:21:22
different conditions, what happens with different 11:21:28
kinds of animals, including ultimately people, if 11:21:30
it's possible to do the studies with people. 11:21:32
So this was -- I don't remember the exact 11:21:34
context in which I used this with Mr. McGuire, but I 11:21:36
think I was using that as a note to explain the high 11:21:38
dose study logic. 11:21:41
Q. And how does that all relate to the 11:21:51
opinions that you expect to give in this case? 11:21:52
A. It's part of the research design process. 11:21:55
Early in an investigation, if there's not a lot of 11:21:57
research in the area to begin with to -- on which to 11:22:00
base the next study -- somebody has to start 11:22:04
somewhere. If there is reason to believe that an 11:22:06
agent may be damaging, such as a chemical agent, then 11:22:14
you might design animal studies with a relatively 11:22:14
high dose exposure, just to see if it has an effect 11:22:17
at all. And if you do, then you would move to 11:22:22
additional studies that might explore the details of 11:22:23
that association, including lower dose exposures and 11:22:25
different kinds of animals, or animals exposed under 11:22:30
different conditions. 11:22:33
Q. All right. Let's go to Number 12. What 11:22:38
does Number 12 say? 11:22:40
A. That says, "Peer review, replication 11:22:42

process, research papers and study sections." 11:22:46
Q. All right. And what is this all about? 11:22:48
A. This came up in the conversation when I was 11:22:49
trying to describe to Mr. McGuire, as I did here 11:22:53
earlier, that the research methods are kind of a big 11:22:57
package. I think of them as a big circle or a ball. 11:23:02
And they are not simply how you design one study, but 11:23:06
they are a collection of studies, and they are a 11:23:09
process by which the community of researchers deals 11:23:12
with that collection of studies. 11:23:19
And that process involves -- pardon me -- a 11:23:19
series of specialist reviews. There are peer reviews 11:23:22
for journal articles, there are peer reviews for 11:23:26
research grants, and those two sets of peer reviews 11:23:29
are done by a cascade of specialists in the area of 11:23:33
investigation, whatever that might be. They usually 11:23:37
involve reviewers who are not limited to just one 11:23:40
narrow area of investigation but have some breadth. 11:23:44
And if it's a research grant, for example, all 11:23:48
features of the science would be reviewed. And if 11:23:51
there were serious liabilities in the research design 11:23:53
that the reviewers felt were not adequate, the 11:23:56
quality of the science had not met minimum standards, 11:24:00

they would recommend against funding it. So for a study to get through the peer review process, it has to go through a fairly severe gauntlet of technical issues in the quality of the science in order to be funded. 11:24:03 11:24:07 11:24:09 11:24:14 11:24:16

Once funded, it goes through some process of completion, and one or more research papers will come from that project. That then goes through another peer review process of reviewers for whatever journal you may be trying to publish the paper in. And in that process, again, you usually have two or three reviewers plus an associate, and maybe a senior editor, whose job it is is to find flaws with the study that would justify a decision not to publish. 11:24:16 11:24:19 11:24:22 11:24:26 11:24:32 11:24:34 11:24:36 11:24:40 11:24:43

And that -- in both cases those peer reviews are based on the rules of science. So if you have done a study, as I mentioned earlier, that was with too small a sample and didn't have sufficient power to detect a presumed effect size, they might argue that that was simply a naive study and didn't meet minimum standards, and would decline to publish it on the grounds that it was not powerful enough to answer the question. If, on the other hand, it might have had a satisfactory sample size, but perhaps there was a flaw in the measurement that was identified, possibly a flaw that the investigators had not recognized, then that may be a basis for miss -- misunderstanding what's going on, because your measures don't have -- are not sufficiently reliable, or valid, and the reviewers might make a judgment there that either the study should not be funded or should not be published. 11:24:48 11:24:51 11:24:54 11:24:58 11:25:01 11:25:05 11:25:09 11:25:12 11:25:15 11:25:17 11:25:19 11:25:22 11:25:24 11:25:31 11:25:33 11:25:35 11:25:40 11:25:42

So the message here is that these reviews are not capricious. They are not based on opinion of whether we like something or dislike something. They're based on the quality of the science being proposed, or the quality of science achieved after completion and submitting some form of a report. That process is extremely difficult, and many, many, many studies don't make it through the combined gauntlet to publication. And the reason they don't is because they have definable errors. And the logic under -- pending the decision not to press forward with the study and fund it, or to press forward with its publication, is that the information included in it would likely be misleading because it's based on error. I'm not sure if I can give a -- a good analogy of that. 11:25:43

11:25:46 11:25:50 11:25:53 11:25:55 11:26:00 11:26:07 11:26:12 11:26:16 11:26:20 11:26:25 11:26:27 11:26:31 11:26:32 11:26:35 11:26:41

Q. I'm just wondering what you mean by "definable error." 11:26:43 11:26:44

A. Such as a invalid measure might be identified, measure that has inadequate reliability. Let me give you an example what the reliability is, a case in point. Many of the studies that we've been looking at, or that I've been looking at, involve a report of exposure to passive smoke. Most of them involve a report where it's simply, "Did you live with somebody who is a smoker?" and some verification that you, yourself, were never a smoker. So you have, for example, a spouse who's living with somebody who's a smoker. That's not a bad measure. 11:26:46 11:26:48 11:26:51 11:26:55 11:26:58 11:27:01 11:27:05 11:27:08 11:27:11 11:27:14 11:27:17

Many people believe it. If you were to test its reliability, that is, if you were to ask people if that -- that condition were true more than once, they would probably answer the same way. And that's a kind of reliability. You get consistency when you ask the same person, "Are you a nonsmoker?" and "Do you live with somebody who smokes?" They would probably say "yes" twice, if asked twice. Or "no," if asked -- if "no" was the right answer, and asked twice. 11:27:23 11:27:26 11:27:26 11:27:30 11:27:32 11:27:35 11:27:38 11:27:41 11:27:43 11:27:47

But if you go back to that same person and say, "How many cigarettes were you exposed to in a day, or a week, or a month, or in the last ten years?" and you would ask that twice, they may give you different answers. And the reason for that is -- the reasons for that may be many, but one of them may be that they can't recall accurately how many cigarettes to which they had been exposed. 11:27:48 11:27:50 11:27:53 11:27:56 11:27:57 11:28:01 11:28:03 11:28:04

So, on the one hand, you have a reliable measure, but it's crude. "Yes or no, I've been exposed," but we don't know how much. We know that you lived with somebody that smoked, but you could have been exposed a lot or a little. Or you could ask about the details and try to get more information about how much exposure took place, but it could be done in such a way that wasn't reliable. 11:28:06 11:28:10 11:28:13 11:28:16 11:28:18 11:28:21 11:28:23 11:28:26

If the study goes forward with a blunt measure that is reliable but not as precise as you would like, it may attenuate the associations found, but it can find at least modest associations. If you go forward with the study that has more precise measure in theory, one that is attempting to get at, say, a more detailed dose measure, but it does so with an unreliable procedure, then it may actually reduce the size of the association to be found. It would increase the error term and, therefore, make it almost certain to be a nonsignificant finding. 11:28:28 11:28:32

11:28:36 11:28:39 11:28:43 11:28:46 11:28:50 11:28:52 11:28:58 11:29:02 11:29:03

So, in a sense, if you design the study, either knowingly or unknowingly, with an inadequate measure, and a reviewer, either at a study section for a grant or in a journal, identifies that error, the way that would normally be handled is they would explain, "We're not going to fund this study, and we're not going to publish the study because you have an error in your measure that is too severe. It would be misleading if we were to go forward with this bad measure. Go back, fix the measure, come back again and we'll reconsider it." And that's generally the way the science works. 11:29:06 11:29:09 11:29:12 11:29:18 11:29:21 11:29:23 11:29:26 11:29:29 11:29:31 11:29:32 11:29:37 11:29:40

In the case of the ETS research, much of the research, as I've seen it, has been based on exposure as defined by living with somebody who was -- who was a smoker. Some of the studies have gone on to try to compute dose measures, or calibrated measures, such as the number of years of exposure, and a few have gone on to try to measure the amount 11:29:45 11:29:49 11:29:51 11:29:54 11:29:58 11:30:01 11:30:05

of time of exposure per day, or the number of cigarettes. I have not seen a study yet which has been designed to look at health outcomes where the more quantitative approaching continuous measure of 11:30:08 11:30:11 11:30:16 11:30:21

exposure, whatever that measure might have been, was also shown to be reliable and valid.

And that would be a normal condition in many studies. You would not only plan the study in a certain way, but you would also plan formal reliability and validity checks of that measure. You would convince me that it is a reliable measure, meaning consistent, and that it's valid, meaning that it's truly measuring what you want it to measure. And that's -- that's an area in which more work could be done in the ETS research field.

Q. Okay. Does the publication peer review process differ depending on who is -- or who has funded a particular study?

A. It can, but normally it does not. That depends on the journal, in the case of a -- of a publication review, the way the journal handles the review. Journals differ in that regard. Some of them are what's known as single blind reviews, where the reviewers may know who the authors of the study are, but the authors do not know who the reviewers are. That's obviously to protect the reviewers. Gives them freedom to make an unpopular decision, even if their colleagues in the field might not like

it.

Q. They don't give their home addresses?

A. Exactly. Some journals, I think preferably, use a double blind review, where neither the authors nor the reviewers know either party. So when I am in a reviewer position like that, I'm reviewing a paper with no authorship on it. I don't know who did it. And it's rare, under either of those conditions, for me to know who funded it. Occasionally that will be somewhere in the document and it may become visible to a reviewer, but it's quite common for that information not to be provided to the reviewer. So normally at the peer review for journal articles, the information about who funded the study may or may not be that public to the reviewers. And that depends partly on the journal, partly on the authors who submit it. If they bury that information somewhere in the text, it may become visible, even if the editors normally remove it.

At the peer review basis, you know, you have kind of a funny situation there. It might arise as a concern where somebody had received funding from a particular agency, but if it goes to NIH, by definition it's being viewed by them, and so it will be funded, or not, by them. So there -- the funding issue isn't an issue there, unless there was some other funding in the history of that investigator that might be of concern. But normally that would be

held up as an independent, you know, issue. You review the science for the science and not based on the funding sources.

Q. Okay. The next one, Number 13, "Two-tail tests," I think we talked about that already. Was there anything different that you talked about with Mr. McGuire and Ms. Frostrom?

A. No. Probably it just came up again in the conversation. I don't remember exactly why I wrote

it down there. 11:33:28
Q. All right. And then Number 14 says "Create 11:33:29
file billings"? 11:33:30
A. Right. That goes back to the dating 11:33:31
information that I haven't done yet, and I haven't 11:33:33
billed them yet. 11:33:35
Q. All right. Number 15 says "Send helpful 11:33:36
materials." Did I read that right? 11:33:39
A. Yes. And he asked me, if I knew of 11:33:41
something that might be pertinent to the case, to 11:33:43
please let him know. Except for the e-mail that I 11:33:45
sent that you just discussed with me earlier, I 11:33:49
haven't sent anything else helpful. 11:33:52
Q. All right. Have you -- did he ask -- did 11:33:56
he ask you not to send anything that was harmful? 11:33:56
A. No. He only asked me to restrict it to 11:33:59
things that were pertinent to the case. 11:34:02
Q. And what things have you sent to -- 11:34:04
A. Just the one e-mail. 11:34:08

Q. That's it?
A. That's it. Oh, I have given him my own 11:34:09
reprints, which you have, I think. That's part of 11:34:10
the material that was given to you. 11:34:13
Q. All right. I think we have the first page 11:34:15
of some of your -- 11:34:16
A. Yes.
Q. -- reprints. 11:34:16
A. Right.
Q. All right. And then if you go up the left 11:34:17
side --
A. Uh-huh.
Q. -- of this document, it looks like there's 11:34:19
two more things here. One of them says "16 IRB." 11:34:21
I'm not sure what that means. 11:34:24
A. IRB is a note referring to the 11:34:25
Institutional Review Board for Protection of Human 11:34:27
Subjects. This actually gets back to the point in 11:34:30
12, except that it's the next level of the peer 11:34:33
review process. In all academic research, for both 11:34:37
animals and people, there is a review board, usually 11:34:43
affiliated with an academic institution. The sole 11:34:47
purpose of that review is to review the science that 11:34:52
is proposed before it is actually conducted to make 11:34:54
sure that a number of conditions are met, ethics 11:34:58
conditions primarily. Those conditions are that the 11:35:03
-- in the case of animals, that they're treated 11:35:09
humanely. In the case of people, that they're 11:35:11

treated humanely and that their confidentiality is 11:35:13
protected, that they are fully informed as to the 11:35:18
possible risks of the study, the possible benefits of 11:35:20
the study, and that the -- in the judgment of the 11:35:24
reviewers, that the possible benefits outweigh the 11:35:26
possible risks to a point that would make the study 11:35:29
likely to be more of a benefit than a harm. And if 11:35:33
it meets those standards, then the study can go 11:35:36
forward. If it does not, this study would not be 11:35:40
allowed to go forward, or at least not without 11:35:43
revision. 11:35:46
So in the peer review process, not only do 11:35:48
you go through the scientific review, say, for a 11:35:49
funding decision, you also go through a ethics 11:35:51

review, which overlaps with some of the issues of the scientific review. They're not entirely independent. And if you meet both of those standards, then presumably the funding can go -- pardon me -- the project can go forward. And then at the tail end, when you finally completed the project, you go through the next review, which is for peer reviewed journal publications. 11:35:54 11:35:58 11:36:02 11:36:04 11:36:08 11:36:10 11:36:12 11:36:14

So this is an attempt, in a sense, to define an extraordinarily conservative system. I know no system -- I know of no system that is as conservative as the research method system. It's entirely designed to accept possible associations -- pardon me -- only after overwhelming evidence of 11:36:16 11:36:18 11:36:22 11:36:25 11:36:29 11:36:36

their validity is in place, and to do so under conditions that are as ethical as we can make them. 11:36:40 11:36:45

Q. Now, earlier when we were talking about the people epidemiology studies, we also -- you also mentioned something about animal studies. And you have -- I think you said that you reviewed some animal studies in connection with the work that you're doing here. Is that true? 11:36:48 11:36:50 11:36:54 11:36:56 11:36:58 11:37:00

A. I've looked at one or two. 11:37:08

Q. Which ones did you look at? 11:37:08

A. I can't remember them here. I could go back and try to find them. I'm not even sure I have them here. They may be in the notes still at home. 11:37:08 11:37:08 11:37:14

Q. Were they -- what notes do you still have at home? 11:37:14 11:37:19

A. Some of the other articles that I referred to here that may not be in this list that I haven't had a chance to go through. 11:37:19 11:37:19 11:37:23

Q. All right. Do you have additional handwritten notes at home that aren't included in the Exhibit -- 11:37:23 11:37:23 11:37:27

A. No, I don't think so.

Q. -- 564 and 565? 11:37:27

A. No, because I haven't done any other reviews yet. I normally -- this kind of -- this kind of note would be made with when I go through and give an article, especially if it looks like it's a very important article that I should look at in detail. 11:37:27 11:37:30 11:37:32 11:37:34 11:37:39

Q. Do you know who the researchers were who did those animal studies? 11:37:42 11:37:44

A. No, I -- 11:37:47

Q. Was it Dr. Witschi? 11:37:47

A. No. I do not believe it was Dr. Witschi, but I do not know. 11:37:48 11:37:51

Q. Were they lung cancer studies, or some other kind of study? 11:37:51 11:37:54

A. I can't remember. I really -- I can find out for you, but I don't have that information today. 11:37:57 11:37:58

Q. Okay. Have you prepared any writings related to this case? 11:38:01 11:38:23

A. No. 11:38:25

Q. Do you intend to prepare an expert report? 11:38:26

A. If asked, I will prepare one. I have not yet been asked. 11:38:29 11:38:31

Q. What writings do you intend to prepare for this case? 11:38:33 11:38:36

A. Except for these kinds of notes, that's 11:38:39

all. I may want to prepare something that would illustrate some of these research methods in some fashion, or bring in something Xeroxed from a textbook. But I was not planning to write up a large document. 11:38:42 11:38:43 11:38:47 11:38:50 11:38:53

Q. When did plaintiff's counsel first contact you about scheduling this deposition? 11:38:59 11:39:00

A. I'm not sure. But I think it probably occurred in my -- my meeting with Dr. -- I mean Mr. 11:39:06 11:39:09

McGuire, where we first discussed it as possibly being at this time. And then I think when I met with Karen about a week ago is when we confirmed that this would be the date. 11:39:13 11:39:16 11:39:18 11:39:21

Q. What have you done to prepare for this deposition? 11:39:29 11:39:29

A. I have reviewed -- most recently I've reviewed some of the studies that -- and some of the reviews that concern passive smoke exposure and cardiovascular disease associations. 11:39:30 11:39:33 11:39:36 11:39:39

Q. Have you completed all work that you need to render your expert opinion at trial? 11:39:47 11:39:49

A. Probably not. No, I haven't reviewed all that they've given me, and I haven't reviewed all that I might find in the literature, if I get additional studies in. 11:39:52 11:39:55 11:39:57 11:40:01

Q. All right. And what more work do you have to do to be ready to render your opinion at trial? 11:40:02 11:40:03

A. I would say two things. I need to review some of that additional literature and make sure that I have a satisfactory sample of that literature completed. In a sense that's just making sense of what I've done and what's not done. And then probably construct some notes, just to get my thinking clear on what I think the literature shows. And -- and then that would either be in a position paper, if it were formal, or informal as my notes here have indicated. 11:40:09 11:40:12 11:40:14 11:40:16 11:40:19 11:40:22 11:40:26 11:40:27 11:40:31 11:40:34

Q. And what do you consider to be a satisfactory sample of the literature? 11:40:35 11:40:37

A. In this case it's what I can find by deadline, I'm afraid. But what I've tried to do is structure my review to take the most recent information, some of the -- what I've identified as best I can as classic papers and reviews of the literature. And where those reviews raise issues about some studies, I may go back and find those studies, if I haven't already reviewed them. 11:40:39 11:40:41 11:40:45 11:40:47 11:40:51 11:40:54 11:40:58 11:41:01

Q. Do you intend to review every epidemiology -- people epidemiology study regarding ETS and cardiovascular -- 11:41:03 11:41:07 11:41:11

A. No. 11:41:12

Q. -- effects? 11:41:13

A. I do not. 11:41:13

Q. How do you intend to select the studies that you review, and reject the ones that you're not going to review? 11:41:13 11:41:16 11:41:20

A. The ones that I would review would be based on currency, based on their classic nature, or if there is a debate about methodology or the believability of their outcomes, then I would go back and look at them. So I would tend to start with the 11:41:20 11:41:22 11:41:25 11:41:28 11:41:31

-- you know, not today's date but maybe a few weeks 11:41:38
ago, couple weeks ago's date, and then run backwards 11:41:40
from that to identify the latest publications. 11:41:44
The other standard I would use is to pick 11:41:46

up the reviews in the literature of the same issue, 11:41:48
look at the logic employed. And, by the way, when I 11:41:51
say "reviews," I also include meta-analyses. Some 11:41:53
people do not call those reviews, but I do. And I 11:41:57
would look at the way they have summarized the 11:42:02
literature, and then I may go back and sample some of 11:42:03
the studies that they have illustrated and work 11:42:06
backwards accordingly. So it's a systematic 11:42:09
procedure, but it is not inclusive of everything. 11:42:20
Q. For lung cancer, people epidemiology 11:42:23
studies, do you intend to review all of the lung 11:42:26
cancer studies? 11:42:30
A. No. I'd use the same procedure. 11:42:30
Q. What about for other health end points? 11:42:33
A. The same procedure. 11:42:37
Q. Which specific other health end points 11:42:39
beyond lung cancer and cardiovascular do you intend 11:42:41
to perform the research for? 11:42:44
A. I don't intend to go beyond what I've 11:42:47
already done in that regard, unless asked to look at 11:42:50
another area. Right now I will concentrate primarily 11:42:52
on the methods employed by the Cal EPA process, speak 11:42:56
to the methods they employed and some of the selected 11:43:02
studies that they relied on. 11:43:06
Q. Cal EPA addressed many different -- 11:43:09
A. Uh-huh.
Q. -- health end points. 11:43:11
A. Correct. 11:43:12

Q. Are you intending to address all of the 11:43:12
health end points or just selected health end points? 11:43:15
A. Selected and general research procedures 11:43:19
that may have been applied to many, if not all, of 11:43:20
the end points they did review. 11:43:23
Q. Which are the selected health end points 11:43:24
that you intend to address? 11:43:27
A. I can speak to some of the lung 11:43:28
associations, and I can speak to the cardiovascular 11:43:30
associations at this time. 11:43:32
Q. Which lung associations in particular? 11:43:33
A. I remember adenocarcinoma, but I'm not sure 11:43:37
of the other kinds of diseases because I don't -- I'm 11:43:41
not a specialist at the pathology end of it. 11:43:43
Q. Lung cancer is certainly going to be one of 11:43:46
them, right? 11:43:49
A. Correct. 11:43:51
Q. Are there any other lung diseases that you 11:43:51
intend to look at? 11:43:53
A. Not specifically. 11:43:54
Q. All right. So really lung cancer and 11:43:55
cardiovascular disease are the two areas that you're 11:43:58
going to specifically look at? 11:44:01
A. That's true. But, remember, when I look at 11:44:02
those things, I'm looking at them as ill health 11:44:04
outcomes. I'm not looking at them from a pathologist 11:44:07
point of view. So I'm not looking at the details, 11:44:11
the nature of the lung cancer. And, frankly, I don't 11:44:15

get excited about whether it's a lung cancer outcome or different kind of disease outcome. What I'm looking for is the design by which the association with the outcome was attained. 11:44:17 11:44:20 11:44:23 11:44:25

Q. And how are you going to review the Cal EPA report to develop your opinions regarding general procedures that were followed for the Cal EPA report? 11:44:27 11:44:30 11:44:31

A. The way I'm -- pardon me. All of my reviews of the individual studies and the Cal EPA report, or other documents, will follow from the rules of logic used for scientific procedures. So I'm looking for how they meet the standards of causality. And that -- that involves, for example, the design of a specific study that I may look at in some detail. It may also involve the process of peer review or consensus judgment that may have been employed to reach some kind of a policy decision. And I can speak to that procedure overall. I'm not sure if that answers your question. 11:44:35 11:44:45 11:44:51 11:44:53 11:44:57 11:45:01 11:45:07 11:45:12 11:45:15 11:45:18 11:45:22 11:45:30

Q. It helps. 11:45:30

A. Okay. 11:45:32

Q. What more research or work do you need to do to be prepared to offer your opinions regarding the general procedures followed by Cal EPA? 11:45:32 11:45:38 11:45:40

A. I need to review some additional articles that I've not yet gotten to. 11:45:44 11:45:45

Q. What types of articles are those? 11:45:48

A. They would be those that concern both lung 11:45:51

disease and cardiovascular disease, and possibly others that I haven't looked at yet, because I don't know what the stack includes, so I don't know what it is. And some of those may not be pertinent to the case, in which case I will identify that and eliminate them. You know, there's -- if I do a Med Line research or something and pull up a reference that turns out to be a misfire, then I'll just select it out. 11:45:54 11:45:56 11:45:58 11:46:00 11:46:03 11:46:06 11:46:11 11:46:14 11:46:17

Q. Just to see if we can pin you down on this one, because we asked you before and I'm just going to ask you again now, in light of all of the work that you have to do for lung cancer, for cardiovascular, and for your opinions regarding the Cal EPA report -- 11:46:19 11:46:21 11:46:23 11:46:26 11:46:28 11:46:32

A. Uh-huh.

Q. -- how long do you estimate it's going to take you to get that work done? 11:46:35 11:46:36

A. Well, given my schedule, I would say two to three weeks at a minimum. If I have to go faster, I can. But it's going to require juggling my other work quite a bit. 11:46:38 11:46:40 11:46:45 11:46:49

Q. All right. So if we were to schedule your deposition -- your further deposition for, say, three weeks from Friday, would you be ready to testify at that time? 11:46:50 11:46:52 11:46:58 11:47:01

A. I could. 11:47:02

Q. Okay. But you're not ready to testify 11:47:03

today about all of your opinions, are you? 11:47:05

A. That's true. 11:47:08

Q. Okay. Now, when you met with Ms. Frostrom last week to discuss your deposition, did you tell her that you weren't ready to discuss all your 11:47:08 11:47:13 11:47:15

opinions? 11:47:18
A. No. I told her that I was going to start 11:47:20
reviewing madly and that I would try to be ready for 11:47:21
this. Which, incidentally, I have done. I mean, I 11:47:26
think I've met that standard. I don't think I've 11:47:29
gotten through it all, but -- 11:47:31
Q. You've tried, but you haven't -- 11:47:34
A. Exactly.
Q. -- you haven't succeeded? Okay. 11:47:40
What else did you discuss with her during 11:47:40
your -- I think it was about a three-hour meeting we 11:47:40
talked about that you had last week? 11:47:43
A. Yeah. Mostly the deposition procedures. 11:47:45
She described the process that we went through early 11:47:48
in the beginning of this where we -- where you 11:47:51
described the process and how it would proceed. I 11:47:55
asked some questions, my sort of Perry Mason view of 11:48:03
what this might be like. I was under the impression 11:48:06
that I would be restricted to yes/no answers. That 11:48:09
-- that was clarified. I mean, I'm not sure how far 11:48:12
the -- you know, we went into some detail about that 11:48:18
kind of thing, but mostly it was to prepare me. She 11:48:20
pointed out that it would be videotaped and that I 11:48:24

should dress accordingly. She did not indicate how I 11:48:26
had to dress. She just told me to dress accordingly. 11:48:29
So it -- it mostly revolved around the process. 11:48:32
There were a couple of interruptions during the 11:48:38
meeting for other business. I mean, not for me but 11:48:40
for her. And -- and then I was finally paged by my 11:48:44
office and told to go back to work. And that's what 11:48:49
ended our meeting. 11:48:52
Q. Okay. All right. Let's -- let's talk a 11:48:54
little bit more about some of your background here, 11:48:56
just to make sure that we understand that fully. As 11:48:59
part of Exhibit 564 your curriculum vitae was 11:49:00
included. 11:49:05
A. Uh-huh. 11:49:06
Q. Is that your most current curriculum vitae? 11:49:07
A. Very close, but not absolutely current. I 11:49:12
haven't -- I don't think we've even typed up what 11:49:15
would be the most current. 11:49:17
Q. What would be on your most current one that 11:49:19
isn't on this one? 11:49:22
A. Let me look real quickly and see. This is 11:49:22
a work in progress. It's never really done. So I 11:49:41
apologize for that, that feature of it. 11:49:46
Q. I must say, with the length of it, I think 11:49:51
it would be hard for it ever to be completely done -- 11:49:53
A. Yeah. 11:49:57
Q. -- and keep it completely up to date.
A. I try not to read it myself. Let's see. 11:49:57

Okay. Okay. This does not yet include the recently 11:50:02
funded study to Dr. Hofstetter from the TRDRP, which 11:50:12
would appear at the end of the list on page 5 were it 11:50:18
to be added, I believe, under "State and County 11:50:21
Support." So that -- that needs to be built in. And 11:50:24
then let me look real quickly. Okay. It looks like 11:50:34
the chapters are complete. That appears -- the end 11:50:47
of those appears at the top of page 10. 11:50:50
And then under the research articles -- 11:50:54
okay. The Paper Number 123 on page 17 is now 11:51:28

published. And I think you have the first page, or a copy of it. And the 122 is now published. And the 121 is now published. Let's see. And the 120 is also published now, I believe. And then there are -- there is one additional paper, one or -- one or two additional papers that have been published and -- or have been accepted and will be published shortly. And at least one of those relates to passive smoke exposure. I can make that available to you. 11:51:32 11:51:39 11:51:47 11:52:04 11:52:10 11:52:17 11:52:20 11:52:22 11:52:25

Q. What is that published -- or what is that paper? 11:52:27 11:52:29

A. They changed the title on me. So I can't -- I mean, the journal did. I didn't. It's -- it's something to the effect of "Decreasing ETS Exposure in Low Income Children," or something to that effect. 11:52:32 11:52:34 11:52:38 11:52:41

Q. Where will that be published? 11:52:43

A. British Medical Journal. It's actually going to be published this week. 11:52:49 11:52:51

Q. And that's not on your resume now, but it will be -- 11:52:53 11:52:56

A. Yes, I need -- 11:52:56

Q. -- in the future?

A. -- to add it. It's been under review, so it didn't get into the listing. 11:52:57 11:52:59

Q. What's the other publication that you have coming out? 11:53:04 11:53:06

A. Let's see if it's here or not. I think it's 123, that's -- yeah, that one is published now. It's the 123. I believe that's the only other one. So some of these that are listed as "in press" are now actually published. That's -- 11:53:07 11:53:09 11:53:12 11:53:19 11:53:21

Q. I'm sorry. One of the ones that I was most concerned about was 124, because if you look at the first page of Exhibit 564, Ms. Frostrom's letter to me, Number 6, I believe that's the same study. Am I reading that correctly? 11:53:22 11:53:25 11:53:29 11:53:36 11:53:42

A. Which one? 124 and which one? 11:53:43

Q. If you look at 124, and you look at the first page of Exhibit 564, article number -- or Number 6, is that the same one? 11:53:46 11:53:49 11:53:55

A. No. The "Trials and Tribulations" paper -- wait a minute, let me see. Make sure I've got these right. It should be in "Tobacco Control." Yeah. Number 125 and the Number 6 are the same studies. 11:54:06 11:54:12 11:54:16 11:54:22

Q. Oh, I'm sorry, I had misspoke. I meant 125. I'm sorry -- 11:54:30 11:54:37

A. Okay.

Q. -- about that. So 125 and Number 6 are the same studies? 11:54:37 11:54:37

A. Uh-huh. 11:54:40

Q. Is that now published? 11:54:40

A. Yes. 11:54:40

Q. All right. We haven't been able to find that one. I wonder if we might be able to get a copy from you. 11:54:40 11:54:41 11:54:44

A. Uh-huh. What I can do is make a copy of all of these available. Okay. 11:54:45 11:54:48

Q. Okay. Now, let's finish working our way through your resume to make sure that we've identified anything else that might be added from page 17 forward. 11:55:15 11:55:19 11:55:21 11:55:24

A. Uh-huh. I frankly don't keep track of all the presentations that are listed, so there may be some that are lost to documentation. This is the best record I have of them right now. And let me look and see what the listing looks like. Looks like 222 is published here with nothing next to it. Yeah. I think this is pretty current. I don't believe we are presenting anything at a -- at a professional conference that goes beyond what's listed here. 11:55:27 11:55:34 11:55:36 11:55:41 11:55:45 11:55:50 11:56:01 11:56:04 11:56:07

Q. One thing I was going to ask you about your resume that I was a little puzzled by, because I didn't understand the -- the term, it's on page 4 of your resume, which is Bates Number 4 of Exhibit 564. 11:56:18 11:56:21 11:56:24 11:56:33

A. Okay. 11:56:48

Q. It's the term "grantsmanship." What does that mean? 11:56:48 11:56:51

A. That's my use of the term for the process of writing and conducting grants, writing and managing grants. So that what -- what is listed under this would be the formal grant submissions that we've made that were funded with either me serving as the principal investigator or as a co-investigator. 11:56:53 11:56:57 11:57:00 11:57:03 11:57:07 11:57:10

Q. So would you be called a grantsman in that case? 11:57:14 11:57:16

A. I think so, in this case. Although most people don't do that. That's my use of the term in this document. But they don't generally refer to me that way. 11:57:16 11:57:19 11:57:21 11:57:25

Q. And then the process is grantsmanship? 11:57:27

A. Exactly. 11:57:31

Q. All right. When did you first become involved in researching -- or research related to tobacco issues? You can refer to your resume -- 11:57:32 11:57:33 11:57:37

A. Right.

Q. -- if that helps. 11:57:44

A. That would have been -- probably the first one would have been with John Elder. Let's see, where is that? If you look on page 4, the same document you were referring to, you see "Project SHOUT." It's towards the bottom, "with Dr. Elder" is in parentheses. "Smokeless Tobacco Prevention in 11:57:44 11:57:48 11:57:51 11:57:58 11:58:01 11:58:05

Youth." That was in -- that was funded in 1987, and we probably prepared that in about 1986 or so. So it was approximately the mid '80s. 11:58:11 11:58:16 11:58:21

Q. Who is Dr. Elder? 11:58:24

A. He's another professor in the School of Public Health, a colleague of mine. 11:58:26 11:58:28

Q. Is he also in the Center for Behavioral Epidemiology and Community Health? 11:58:31 11:58:37

A. He actually directs the parallel center down the hall from me. 11:58:37 11:58:39

Q. What's his called? 11:58:41

A. Behavioral and Community Health, I think. I can't remember. 11:58:44 11:58:47

Q. All right. How did you -- how did you become involved in this tobacco research? 11:58:50 11:58:50

A. The study with him? 11:58:54

Q. Yes. 11:58:56

A. He invited me to assist as a co-investigator. And what that means is I would serve as a person to assist with things like the 11:58:56 11:58:58 11:59:02

design, the methods employed, everything from measurement systems to the intervention procedures, assisting with the manuscript preparation at the end of the study. 11:59:04 11:59:08 11:59:12 11:59:16

Q. What type of study was that? 11:59:17

A. This was a school-based study where kids were being provided with education about tobacco in order to persuade them not to start, or to quit, if 11:59:18 11:59:21 11:59:25

they had already started. And was subsequently published in the American Journal of Public Health. There were a number of publications, but the primary paper was in the American Journal of Public Health. It's listed in my C.V. here, but I don't remember which article -- which number it is. 11:59:30 11:59:33 11:59:35 11:59:39 11:59:41 11:59:43

Q. I'm sure I saw it there. 11:59:45

A. But it's under "Elder, et al." 11:59:46

Q. Okay. What were the results of that study? 11:59:48

A. The results showed that with peer and telephone prompting in and around and following the school-based education program, there was a lower rate of tobacco initiation. I don't actually remember the rates for tobacco cessation. There may have been a change in that as well, but I'd have to actually go back and read it. It's been a number of years. 11:59:56 12:00:01 12:00:06 12:00:09 12:00:13 12:00:15 12:00:18 12:00:20

Q. What was your next research involved with tobacco issues? 12:00:22 12:00:25

A. Let's see. It should be here, I believe. These may not be -- yeah. Okay. Here's the date. 1990 is the first one listed under the "State and County Support." And -- yeah. That -- that study was looking at passive smoking reduction in asthmatic children and funded by the TRDRP. And that was in 1990. 12:00:28 12:00:33 12:00:42 12:00:45 12:00:56 12:01:01 12:01:04

Q. What was that study about? 12:01:07

A. We obtained kids who had asthma from 12:01:08

Kaiser, and from a large allergy clinic here in town, a few from the Navy. And worked with their families to counsel the smoking parents to smoke away from the child. That is, if they were going to smoke, to not smoke when the child was present. And that counseling procedure was our first foray into the passive smoke business. There was a small pilot study done before that, but first funded study. And we published this one in CHEST, I believe, as I noted earlier. And what we found was that there was a reduction in exposure as measured by the parents' report. And the parents' report in that study was validated by an air dosimeter for nicotine exposure in the home. And those analyses were conducted by Brian Lederer and Kathy Hammond. 12:01:17 12:01:20 12:01:21 12:01:25 12:01:27 12:01:29 12:01:35 12:01:37 12:01:42 12:01:47 12:01:50 12:01:54 12:01:57 12:02:02 12:02:06

Q. Does that study serve, or will that study serve, as the basis for any of the opinions that you intend to offer in this case? 12:02:21 12:02:25 12:02:26

A. That study, and subsequent studies, may have bearing on my opinions regarding measurement issues in the overall research design issues. It probably won't have any direct bearing on ill health outcomes. There -- the studies that we've designed so far have been primarily aimed at looking at change in exposure patterns, rather than health outcomes. 12:02:30 12:02:33 12:02:35 12:02:41 12:02:44 12:02:49 12:02:52

In this study, and one that's going on now, we do -- we did, and we are collecting information about the symptoms of asthma that may be experienced by the 12:02:55 12:02:59 12:03:02

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children involved. But the study is not designed with sufficient power to be certain of finding associations with health outcomes. So it goes back to the design issue I mentioned earlier. So while we might explore that, it would be viewed as an exploratory examination of possible associations with, say, asthma severity. 12:03:04 12:03:07 12:03:10 12:03:14 12:03:17 12:03:18 12:03:21

In this study we did find, as I recall, I'd have to go back and read the paper, a modest to weak correlation between reduction -- or between exposure level and asthma symptoms. And I'd have to go back and read it to figure out whether it was a pulmonary -- pulmonary function test or whether it was reported asthma symptoms. I frankly don't remember. 12:03:23 12:03:27 12:03:31 12:03:35 12:03:41 12:03:42

THE REPORTER: Or whether it was what?

THE WITNESS: Pulmonary function measures, or asthma symptoms. Pardon me. 12:03:49 12:03:50

BY MR. CAFFERTY:

Q. With respect to the SHOUT work -- 12:03:59

A. Uh-huh.

Q. -- that we talked about a moment ago, does that report -- or will that report serve as the basis for any of your opinions in this case? 12:04:01 12:04:04 12:04:08

A. No. 12:04:09

Q. Following this passive smoking study that we were just talking about, what was the next tobacco-related research that you performed? 12:04:11 12:04:16 12:04:18

A. I think it was the prevention study. Yeah. 12:04:21

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It's listed next on there, and it's listed as $2 million. So that counts the institutional overhead. So when I told you earlier it was about 1.5 million, I was speaking of direct costs. So if you look at the second listing under "State and County Support" on page 5, you'll see "Clinician-Initiated Smoking Prevention: A Controlled Trial." That was funded in '91. 12:04:28 12:04:31 12:04:36 12:04:39 12:04:42 12:04:44 12:04:48 12:04:52

Q. By the way, what's the difference between a principal investigator and a co-investigator? 12:04:54 12:04:57

A. A principal investigator is the person who's responsible for the study. The grant is actually awarded in the name of the principal investigator and the institution through which the money flows. So there is, in a sense, a fiscal agent, which is the institution, and then something analogous to a C.E.O., which is the P.E.I. -- the P.I., pardon me. Where I run the study and I have fiscal responsibility for the study, and jointly with the institution. 12:04:59 12:05:01 12:05:05 12:05:06 12:05:10 12:05:14 12:05:15 12:05:19 12:05:22 12:05:25

The co-investigators are my assistants at the science level. Occasionally you'll see somebody listed as a co-P.I., sometimes that's honorific, where they are senior investigators, have a lot of responsibility on the project but may or may not be recognized by the funding agency as having fiscal responsibility. Occasionally the funding agency will grant a formal co-P.I. contract. I have never been 12:05:26 12:05:29 12:05:33 12:05:37 12:05:41 12:05:43 12:05:46 12:05:48

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in a formal co-P.I. contract with fiscal 12:05:53

responsibility, nor has anyone working as a co-P.I. for me been in such a role. Contrasting that with Dr. Elder, whom, I believe, has been in a formal co-P.I. relationship where there was fiscal responsibility for both -- 12:05:59 12:06:03 12:06:07 12:06:13 12:06:14

THE REPORTER: I'm sorry. Dr. Elder, who has been in a --

THE WITNESS: A formal co-P.I. relationship where both co-P.I.'s had fiscal responsibilities. 12:06:15 12:06:16

BY MR. CAFFERTY:

Q. You and I obviously talk fast. We have to -- 12:06:19 12:06:22

A. Sorry. 12:06:22

Q. -- try to slow down a little bit. 12:06:22

A. Yeah. 12:06:25

Q. I don't want to get hit in the head with that water glass. 12:06:25 12:06:27

All right. So looking at the -- the study that was "Reduction of Passive Smoke in Asthmatic Children," you are listed as principal investigator. So that means you're the one who received the grant -- 12:06:30 12:06:33 12:06:37 12:06:39 12:06:42

A. Correct.

Q. -- and was responsible for the study? 12:06:42

A. That's right. 12:06:44

Q. Likewise for the other one "Clinician-Initiated Smoking Prevention in a 12:06:44 12:06:46

Controlled Trial," you also were the person who got the grant and was responsible for carrying out the study? 12:06:52 12:06:52 12:06:55

A. Correct. 12:06:55

Q. All right. So that's -- that's the third one that you did, is the "Clinician-Initiated Smoking Prevention in a Controlled Trial." What was that research about? 12:06:55 12:06:57 12:06:59 12:07:01

A. That one was looking at the children who were preadolescent, or early adolescence, and who were receiving clinical care from orthodontists in southern California. And the reason orthodontists, is because orthodontists see a lot of kids and see them frequently. So we could get a large sample. And that study recruited over 17,000 youth. And the analysis was based on -- I -- I can't remember. I think a final end size of about 15,000. 12:07:02 12:07:07 12:07:10 12:07:14 12:07:17 12:07:20 12:07:23 12:07:28 12:07:31

Q. What do you mean by "end size"? 12:07:34

A. Sample size, pardon me. 12:07:36

Q. We've got P and N's. "N" means sample size. Okay. 12:07:40 12:07:44

A. Yes, it does. That study selected a number of orthodontic offices, there were 154 altogether, I believe, and divided the offices into two groups. A group that were to receive instruction in how to advise kids not to start smoking, and the other group was to continue to do normal orthodontic care. And that assignment was based on a random assignment 12:07:44 12:07:47 12:07:52 12:07:55 12:07:58 12:08:04 12:08:07

procedure. And then the kids were recruited and asked at the beginning of the study their smoking history and some of their health behavior history, such as diet and exercise. And they were then asked those same kinds of questions two years later. And we contrasted the proportion who began smoking. And 12:08:11 12:08:14 12:08:16 12:08:20 12:08:23 12:08:26

that study was published in the American Journal of Public Health. 12:08:33 12:08:36

Q. What did you find as a result of that study? 12:08:36 12:08:37

A. We found mixed results. What we found was a nonsignificant difference between the initiation of smoking rates for those in the experimental or counselled group versus those in the uncounselled or control group. However, when we did exploratory analyses following that analysis up, we found that only about -- that the orthodontists in the experimental group only provided about 60 percent of the, quote, prescriptions that they were supposed to have handed out. They were to write a prescription saying "Please don't start smoking," and they were to do that eight times over two years. In fact, they only provided about 60 percent, or a little bit more than four prescriptions. 12:08:37 12:08:41 12:08:44 12:08:47 12:08:52 12:08:56 12:08:58 12:09:01 12:09:04 12:09:07 12:09:09 12:09:11 12:09:14 12:09:18

We then conducted a dose response analysis, and the dose response analysis showed that those kids who had received -- I believe it was five or more prescriptions over the two years, had a significantly 12:09:19 12:09:22 12:09:24 12:09:29

lower initiation rate than those kids who had not. 12:09:33

So we're left with mixed information from this trial. It would suggest that the formal analysis says that clinicians counseling doesn't make a difference in kids starting to smoke. The exploratory analysis suggests that if the doctors did a complete job, it might work. And -- and that study needs to be replicated to resolve that mixed information. It won't be replicated by TRDRP. 12:09:37 12:09:39 12:09:43 12:09:46 12:09:49 12:09:51 12:09:56 12:09:59

Q. Why not? 12:10:05

A. Because of the budget. They generally don't assign that kind of budget in the state of California anymore, and their policy is to fund smaller studies as a rule. 12:10:06 12:10:08 12:10:11 12:10:13

Q. Who will -- who will replicate it, if anyone? 12:10:14 12:10:17

A. If anyone, it will probably be done by NIH funding, and it would probably be done outside of the State of California for reasons of design. It would be easier to do this study under conditions where there are higher rates of initiation, and that might be true here. 12:10:17 12:10:21 12:10:24 12:10:28 12:10:30 12:10:33

Q. And by "initiation" you mean -- 12:10:34

A. Smoking.

Q. -- kids beginning to smoke? 12:10:36

A. Uh-huh. 12:10:38

Q. Does any of the work that you performed as part of this clinician -- clinician-initiated smoking 12:10:40 12:10:42

prevention study serve as the basis for your opinions in this case? 12:10:46 12:10:50

A. Only in general design background, but not in terms of content. No. 12:10:51 12:10:54

Q. All right. What is the next tobacco-related research that you performed? 12:10:55 12:10:57

A. All right. I think that will be in the federal list, if I'm remembering correctly. So that actually appears in advance of the list you're reading. If you look on page 5 at the top of the page, and come down about an inch and a half, you'll 12:11:01 12:11:02 12:11:07 12:11:09 12:11:17

see "Ninos Sanos Reducing ETS Exposure in Latino Asthmatics," and that was funded in '96. And that study is ongoing right now. 12:11:20 12:11:26 12:11:31

Let me check something, though. Because if you also look under the "State and County," you'll see that in -- well, that was '94. We were funded by TRDRP to extend the original passive smoking study that was funded by TRDRP for a follow-up, which means we simply did additional measures to see whether the change that was observed in the original study was sustained. 12:11:36 12:11:38 12:11:42 12:11:45 12:11:51 12:11:55 12:12:01 12:12:01

So we were funded by NIH to extend our passive smoking counseling intervention to Latino asthmatics in '96, and in '94 we had been extended to do more follow-up analysis of the original TRDRP. So the next one would have been the extension grant from TRDRP, followed closely by the NIH grant for passive smoking. 12:12:05 12:12:06 12:12:11 12:12:21 12:12:24 12:12:27 12:12:32

Q. So the NIH grant is separate from the follow-up study? 12:12:32 12:12:35

A. Correct. Funded by a different agency. It's a different -- different sample entirely. 12:12:37 12:12:40

Q. All right. Let's drop back then to the follow-up study that you did with the -- 12:12:42 12:12:44

A. Okay. 12:12:46

Q. -- TRDRP funding. And it looks to me like that's what, 283,000? 12:12:46 12:12:50

A. Correct. 12:12:53

Q. So that's a smaller study than you did initially, about half of what you did initially, correct? 12:12:53 12:12:55 12:12:58

A. Yes, this -- the funding was simply to go back and measure people again. So this was almost exclusively a measurement and analysis money. 12:12:59 12:13:02 12:13:05

Q. How did you do that? 12:13:08

A. We reinterviewed people and measured them again at a later date. The follow-up analysis gave us approximately -- I think it was an 18-month follow-up. So we were able to answer questions about whether the reduced exposure to children was sustained for as long as 18 months. I'm -- I'm not remembering precisely. I believe the study time was two years, but the follow-up period was 18 months, I believe, if I recall it correctly. 12:13:09 12:13:12 12:13:15 12:13:19 12:13:21 12:13:23 12:13:29 12:13:31 12:13:35

And we did a small assessment of a minimal intervention in that follow-up, where we had given people in our control condition some information about how to reduce their child's exposure, and then assessed whether they had made any improvements in exposure over the follow-up period as well. 12:13:37 12:13:41 12:13:44 12:13:47 12:13:51 12:13:54

Q. And what conclusions did you reach as a result of that study? 12:13:59 12:14:01

A. That study showed that the original experimental group that had received counseling to reduce passive smoke exposure was able to sustain most of the reduced exposure through the follow-up period, which, in our opinion, was one of the first studies to show that. Most behavior change studies end up showing that when the assistance, counseling, whatever the services might be, are discontinued, things tend to reverse toward preservice conditions. 12:14:05 12:14:07 12:14:09 12:14:14 12:14:17 12:14:20 12:14:23 12:14:27 12:14:31

In this case it looked like a longer lasting effect. And we speculated that that might have been because these kids were still undergoing asthmatic care from their routine allergist or physician, and that might have had some ongoing support mechanism. But we -- we did not -- we were unable to measure that precisely, so we couldn't say that with certainty. 12:14:35 12:14:40 12:14:42 12:14:45 12:14:49 12:14:52 12:14:55

Q. Will your follow-up study provide any basis for the opinions that you will offer in this case? 12:14:59 12:15:02

A. The follow-up study, as well as the other ETS studies, contributes mostly to my understanding of some of the measurement difficulties in passive 12:15:05 12:15:08 12:15:11

smoke studies in general. 12:15:14

Q. What do you mean by "measurement difficulties"? 12:15:17 12:15:20

A. How to measure exposure. 12:15:20

Q. Let's talk about the NIH study -- 12:15:30

A. Okay. 12:15:33

Q. -- NIH-funded study, the "Ninos Sanos." 12:15:33

A. Sanos.

Q. Sanos, or Sanos? 12:15:37

A. Sanos. 12:15:38

Q. Sanos. What does that mean, children -- what's Sanos? 12:15:39 12:15:43

A. I can't do that. I don't remember. I didn't name it. 12:15:44 12:15:47

Q. All right. "Reducing ETS Exposure in Latino Asthmatics," what's that study about? 12:15:49 12:15:50

A. That study is a replication of the state-funded study, except that it involves Hispanic kids who are asthmatic. And exclusively Hispanic kids. They are also very low income. So it's a high risk population that tends to be medically underserved. And in that study we were trying to tailor the counseling procedures to the families where the child was exposed. 12:15:54 12:15:57 12:16:01 12:16:06 12:16:09 12:16:12 12:16:16 12:16:18

There were some important differences in the design of this study beyond just the sample nature. In the original study conducted by TRDRP funding, the -- we designated a primary parent, or 12:16:21 12:16:23 12:16:26 12:16:29

target parent. That target parent was the person with whom we worked and provided most of the counseling. And we also required that the child be exposed to that target parent smoking in order to qualify for entry into the study. 12:16:38 12:16:42 12:16:44 12:16:46 12:16:49

In this current study with Hispanic families, the pattern of smoking is quite a bit different among Hispanics, where men tend to be the predominant smokers, and only a very small proportion of women are -- at least adult women are smokers. Consequently, we did not feel we could restrict the study to children who were exposed to smoking from their mother. So we, in this case, allowed families to come in if the child was exposed to tobacco from either their father or their mother or another family member in the home. 12:16:51 12:16:54 12:16:59 12:17:02 12:17:05 12:17:09 12:17:14 12:17:22 12:17:22 12:17:25 12:17:26

And, in fact, this study has approximately 30 percent of the children were exposed to cigarette smoke from their mother, which is a substantial departure from what we were doing with the other study. And since young children tend to be around 12:17:27 12:17:31 12:17:35 12:17:38 12:17:41

the mother more often than the father, it means that 12:17:44
the level of exposure with the previous study was 12:17:47
probably higher than would be true for this study. 12:17:50
And we are not yet -- we have not gone into the 12:17:52
analysis far enough yet to confirm that, but that's 12:17:55
what I suspect. 12:17:58
Q. When will this study be completed? 12:17:59

A. We're finishing it now. The intervention 12:18:01
component is completed, and we're collecting some 12:18:06
final measures. We're in the process of cleaning 12:18:08
data and starting to run analyses now. 12:18:12
Q. What do you mean by "cleaning data"? 12:18:14
A. Cleaning data is a process where we -- 12:18:17
where we've collected the data, say in interview 12:18:18
form, and then we have to enter it for computer 12:18:21
analysis. In the entry process there may be typing 12:18:23
errors. We go back and double check those for 12:18:26
errors. If we find those errors, we go back, find 12:18:30
out what the correct response should have been, and 12:18:34
then we correct it. We don't make up the data. That 12:18:36
isn't what cleaning means. 12:18:39
Q. I didn't suggest otherwise. I just hadn't 12:18:40
heard the term before. 12:18:43
A. It's actually a common term in the field. 12:18:44
Unfortunately, I could see how it could be 12:18:46
misunderstood. 12:18:49
Q. Okay. Have any reports been published to 12:18:51
date regarding this study? 12:18:55
A. Yes. We were able to do a small study, I 12:18:56
think it's listed in the -- in the bibliography, 12:19:02
where in the early stages of the study we provided 12:19:07
all of the families, whether they were in the 12:19:09
counseling group or not -- pardon me -- with general 12:19:11
overview education on asthma management. So as a 12:19:16
ethical standard we felt that it was important to 12:19:22

advise both the control and those who were receiving 12:19:24
ETS exposure counseling with information on how they 12:19:27
could better control the child's asthma. 12:19:31
This includes information about avoiding 12:19:33
all kinds of triggers that might elicit an asthma 12:19:35
attack, such as pet dander, mites, house dust. It 12:19:39
would also include advice not to be exposing your 12:19:46
child to passive smoke, you know, fireplace smoke, 12:19:49
other sources of smoke exposure. And it also spends 12:19:55
a bit of time teaching them something about how to 12:20:00
use preventive medication and emergency or rescue 12:20:03
medication in the management of asthma. And so all 12:20:09
of these kids were provided the -- that kind of 12:20:11
education early on. And we analyzed in a pre- and 12:20:14
post- fashion the change, and knowledge, and 12:20:18
procedures that resulted immediately after that 12:20:21
education was completed. 12:20:23
And I can't remember where that was 12:20:25
published. I think that one -- yes, that one is 12:20:28
Number 120 in the publication list. And it was 12:20:38
published in "Patient Education and Counseling." And 12:20:42
that's now -- I believe that's published, even though 12:20:46
it says "in press" on this version. 12:20:49
Q. So that's Jones, Wahlgren, Meltzer, Meltzer 12:20:53
and Hovell? 12:20:55
A. Correct. 12:20:57

Q. Okay. Will the "Ninos Sanos" study form the basis of any opinions that you might give in this case? 12:20:57 12:21:07 12:21:10

A. Only in the -- again, like I said earlier, only in sensitizing me to some of the procedures and difficulties of measuring ETS exposure. 12:21:15 12:21:16 12:21:19

Q. All right. What's the next tobacco-related research that you've done after "Ninos Sanos"? 12:21:23 12:21:25

A. All right. Now I think -- I'm not sure about the sequencing. So if I've misinformed you, we may have to correct it. All right. Okay. Yeah, the next one I believe is on page 6, which is "Maternal ETS Exposure Among WIC Infants." And that is about the third listing down from the top. And it was funded in 1995. So that may have fallen between the other two. I can't remember the dates exactly. And that project was funded by the Robert Wood Johnson Foundation as part of their smoke-free families research program. 12:21:27 12:21:29 12:21:33 12:21:50 12:21:54 12:21:57 12:22:03 12:22:07 12:22:09 12:22:12 12:22:14

Q. Who is the Robert Wood Johnson Foundation? 12:22:16

A. Robert Wood Johnson is the largest health service and health research foundation in the country, prior to Bill Gates's recently developed foundation. They're based out of Newark, New Jersey, I believe. 12:22:20 12:22:23 12:22:26 12:22:31 12:22:38

Q. Who is Robert Wood Johnson? Is that Johnson & Johnson? 12:22:39 12:22:41

A. Yes, it extends from the Johnson & Johnson company. It's an independent nonprofit foundation. 12:22:42 12:22:44

Q. Are they active in antismoking activities, the foundation? 12:22:48 12:22:50

A. They're active in producing -- pardon me -- funding research that concerns medical care in general. And tobacco is one of their concerns in that -- in that large portfolio, but by no means is it limited to that. 12:22:51 12:23:00 12:23:00 12:23:04 12:23:05

Q. Are they on the antismoking side of the issue? 12:23:07 12:23:09

A. My involvement with Robert Wood Johnson is strictly as a researcher, and my involvement in that context has followed the NIH types of research, where it is peer reviewed and, if peer reviewed and accepted, is funded by them for conducting objective science. If they're involved in other policy-making issues for tobacco, I'm not now party to that. 12:23:10 12:23:13 12:23:15 12:23:19 12:23:21 12:23:26 12:23:28

Q. What does "WIC" mean? 12:23:32

A. That's the women, infant and children's federal program for low income families, and provides food vouchers and limited nutrition education as a federal subsidy for low income families. 12:23:35 12:23:37 12:23:41 12:23:47

Q. Okay. What was the study about? 12:23:52

A. This study was an extension of our previous passive smoking studies, where in this case we were examining whether our counseling procedures in order to reduce the child's exposure to their parents' exposure -- pardon me -- exposure to the parents smoking would work in children that did not have asthma or pulmonary disease, so far as we knew. 12:23:54 12:23:57 12:24:00 12:24:04 12:24:08 12:24:11 12:24:13

Again, we were working with a low income and high risk population, but this group was otherwise 12:24:18 12:24:20

healthy. And that is the study which is about to be published in the British Medical Journal. This -- this grant is completed, and that paper is coming out shortly. 12:24:23 12:24:28 12:24:31 12:24:35

Q. What conclusions did you reach? 12:24:36

A. What we showed, and what we did differently in this study, other than the sample being free of asthma, we were able to afford the use of urine cotinine analyses as an additional measure of exposure beyond that of reported measures. The cotinine analyses were conducted by the Centers for Disease Control using what I believe to be then, and I believe now to be, the state of the art for cotinine analyses. So what that provided us was a objective biological measure of exposure, in addition to the reported measure from the parents. And what we found was a reported decrease in exposure in both the control and the experimental group and the decrease was greater in the experimental group than in the control. But both got better. 12:24:38 12:24:42 12:24:44 12:24:51 12:24:53 12:24:57 12:25:01 12:25:03 12:25:06 12:25:13 12:25:16 12:25:22 12:25:28 12:25:30 12:25:33

The cotinine analysis was a little bit more paradoxical. What that showed was a small decrease in the experimental group, and a very large increase in the control group, which suggested that the study was successful in preventing an increase in cotinine exposure -- or, pardon me -- tobacco exposure that 12:25:36 12:25:38 12:25:42 12:25:45 12:25:51 12:25:54

results in the cotinine. Or, depending on which variable you believe, that if you believe the reported measure, then the results imply that simply measuring these things and sensitizing people may cause some decrease. And when we do the counseling, it causes an even greater decrease in exposure. The results are open to some speculation as to which way things are working. 12:25:57 12:26:00 12:26:02 12:26:07 12:26:09 12:26:13 12:26:17 12:26:20

One of the problems with the reported measures is that we're not certain of their validity. And we have run formal validity associations and published them, and they run as modest correlations with cotinine and nicotine analyses. The problem with the cotinine analysis, however, is that it may be measuring exposure that's not limited to what the parents can see. So if you're in the room smoking a cigarette and your child's there, you can probably report that pretty accurately. But what you may not be sensitive to is that that plume of smoke may drift down the hall to another room, and your child may be exposed to some level of that same smoke, and you would not report it because you were essentially unaware of it. But the cotinine would still be picked up as a metabolite of the exposure that may be indirect, meaning not necessarily visible to the parent. And also children may be exposed to sources when the parents aren't around, caretakers, baby-sitters, somebody else. 12:26:21 12:26:23 12:26:26 12:26:30 12:26:32 12:26:38 12:26:41 12:26:44 12:26:47 12:26:49 12:26:53 12:26:56 12:26:59 12:27:02 12:27:04 12:27:07 12:27:11 12:27:13 12:27:16 12:27:19

So we're not sure exactly why the two measures don't show exactly the same pattern, and that will be the basis of probably some future research, either by us or other people. But, in either case, this study does show that by either measure the counseling shows a benefit. It's just that the nature of the benefit is different. 12:27:20 12:27:23 12:27:27 12:27:28 12:27:32 12:27:36 12:27:40

Q. Okay. Is this the only study in which 12:27:42
you've used urine cotinine to determine -- or as a 12:27:45
measure of ETS exposure? 12:27:50
A. No. This study started before the current 12:27:54
Ninos study, "Ninos Sanos" study funded by NIH. And 12:27:57
we are using the same cotinine measure in that study, 12:28:06
partly based on our experience in this study. Pardon 12:28:06
me. But those are the only two that we've used so 12:28:09
far. We have another study that -- two other studies 12:28:11
concerning passive smoke where we will also be using 12:28:15
cotinine assays, but this was the first. 12:28:19
Q. All right. Now, you have got two others. 12:28:23
Are we going to get to those in the list of grants? 12:28:25
A. We can. 12:28:28
Q. Ultimately. Why don't we take our break 12:28:29
for lunch now, and -- to go to our meeting over with 12:28:31
-- with the court, and then we'll be back and we'll 12:28:33
pick up with that. 12:28:36
A. Okay. 12:28:37
Q. Thank you. 12:28:38
THE VIDEOGRAPHER: This concludes Tape 2 of 12:28:39

the videotape deposition of Dr. Melbourne Hovell. 12:28:41
Off the record at 12:27 p.m. 12:28:44
(Whereupon, the lunch recess was taken at 12:30
p.m.)
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SAN DIEGO, CALIFORNIA; MONDAY, JULY 31, 2000
4:25 P.M.

THE VIDEOGRAPHER: This is Tape 3 of the 16:24:29
videotape deposition of Dr. Melbourne Hovell. Back 16:24:30
on the record at 4:23 p.m. 16:24:34
16:24:37
FURTHER EXAMINATION BY MR. CAFFERTY:
Q. Dr. Hovell, before we took our break at -- 16:24:37
for lunch time and for the court hearing that we just 16:24:39
attended, we were going through the tobacco-related 16:24:42
research that you have been involved in, and I think 16:24:47

we got up to the fifth one, which was the "Ninos Sanos" project. And then we had talked about the sixth one, which was the "Maternal ETS Exposure Among WIC Infants." And I don't know if I asked you, so I'll ask you now, will the "Maternal ETS Exposure Among WIC Infants" study serve as the basis for any of your opinions in this case? 16:24:50 16:24:53 16:24:55 16:25:02 16:25:07 16:25:10 16:25:14

A. Yes. Insofar as some of the information we've learned in the course of conducting that study will pertain to measures of ETS exposure. Otherwise, probably not. 16:25:16 16:25:19 16:25:21 16:25:26

Q. Okay. So it's like the other studies -- 16:25:28

A. Correct.

Q. -- it's only about measurements, the other conclusions are really not relevant to your opinions? 16:25:30 16:25:32

A. Yes, it's not about the health effects of 16:25:35

exposure. 16:25:38

Q. All right. And then what is the next tobacco-related research that you did after the "Maternal ETS Exposure Among WIC Infants"? 16:25:40 16:25:41 16:25:44

A. All right. On that one we have to move to the "federal" again. Let's see if I can figure out how to do that on here myself. Okay. All right. If you look on page 5, also your stamped Number 5, about four or five down from the top, it says "Infant ETS Exposure: Clinic-Based Maternal Counseling." Do you find that one? 16:25:50 16:25:52 16:25:55 16:26:11 16:26:16 16:26:20 16:26:26

Q. "Healthy Babies Project"? 16:26:27

A. Yes. That project is in the final stages now. That was funded by the Health and Human Services part of the federal government. And within that the Maternal and Child Health Division within the Health and Human Services. And, hence, the MCH PHS and following grant number there. 16:26:28 16:26:31 16:26:34 16:26:37 16:26:41 16:26:46

That study involves two clinics here in San Diego County where what we have done is asked the two clinics to provide staff who would conduct the counseling of the sort that we had done in some of our previous ETS studies. And what we're doing is evaluating whether the conduct of counseling as provided by community clinic personnel is as effective as what we have found when we were conducting it with research personnel. And that study is in the final stages of data collection, and 16:26:49 16:26:54 16:26:57 16:27:00 16:27:03 16:27:07 16:27:10 16:27:14 16:27:17 16:27:21

we will start analyses shortly. So that one is nearing the end but has not yet been completed. 16:27:23 16:27:27

Q. How did you do that study? 16:27:31

A. That study involved randomly assigning families to either a control condition or a counseling condition, much as the previous ones had been done. We assisted in the recruitment of families who were receiving their medical care from the two participating community clinics. And then staff at those community clinics were to deliver the counseling program. And that's sort of an overview. We were responsible for collecting measures, both interview measures and cotinine measures, on all of the children in the families who were participating. 16:27:33 16:27:35 16:27:39 16:27:41 16:27:44 16:27:47 16:27:50 16:27:53 16:27:58 16:28:01 16:28:05

Q. Okay. Have you prepared any reports regarding this study? 16:28:08 16:28:13

A. No publications yet. We're just in the 16:28:16

stage of analysis now. There may have been one or two public presentations at a conference. I'd have to go back and search the end of this bibliography, or what we have in the office, to be sure. 16:28:18 16:28:22 16:28:27 16:28:32

Q. Okay. And I see from that one, that one is 1,133,000 -- 16:28:34 16:28:38

A. Right.

Q. -- is the total amount of that grant? 16:28:39

A. Uh-huh.

Q. All right. Now, what is the next tobacco-related research? 16:28:41 16:28:43

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A. If you drop down to the end of that category, about in the middle of the page, you'll see another "WIC Families Who Smoke: Behavioral Counseling Program." 16:28:44 16:28:45 16:28:49 16:28:50

Q. It's the last one under "Federal"? 16:28:51

A. Correct. 16:28:53

Q. "State"?

A. And that one has just been awarded recently, and you will see that that was January of 2000. And that study is an expansion of our research effort following the ETS theme that we've already been doing. What this one does differently is that we will be conducting it, so it will not be conducted by existing community clinics. Rather, we will go back to the WIC population that we had used earlier. 16:28:54 16:28:56 16:28:57 16:29:03 16:29:06 16:29:09 16:29:12 16:29:15

And in that study what we will do is provide counseling to reduce ETS exposure. And then for those parents who wish, we will extend that to cessation counseling as well. So we're testing a combination of ETS reduction, or exposure reduction counseling, plus tobacco smoking cessation counseling in that study. Again, the design is very similar to the previous one. We're testing that combined counseling program against a control condition. 16:29:17 16:29:20 16:29:23 16:29:27 16:29:33 16:29:35 16:29:38 16:29:46 16:29:46

Q. In the earlier one, the earlier WIC study was funded by the state; this one's funded by the federal, correct? 16:29:50 16:29:53 16:29:56

A. The earlier WIC I think was -- 16:29:57

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Q. Oh, it was Robert Wood Johnson? 16:29:59

A. Robert Wood Johnson, yes. Yeah. 16:30:01

Q. All right. And this one -- 16:30:03

A. And this one is federal, as well. This is, again, the MCH bureau of HHS. 16:30:04 16:30:07

Q. What does "MCH" stand for again? 16:30:10

A. Maternal and child health. 16:30:13

Q. So this looks like it's a brand new study that's going to be performed over the next, what, four years? 16:30:20 16:30:22 16:30:25

A. Yes, four or five. It will probably take a fifth year. They -- they would not fund us for more than four. But we will ask for a fifth year, almost certainly. 16:30:26 16:30:27 16:30:30 16:30:33

Q. Will you get more funding for that fifth year? 16:30:34 16:30:37

A. If -- it'll be competitive. If -- if the request is judged suitable, yeah. It would not be automatic. 16:30:37 16:30:40 16:30:43

Q. What would you anticipate the fifth year funding would be? 16:30:43 16:30:46

A. Approximately the equivalent of one-fourth 16:30:46

of this, a little bit less probably, because it will be mostly final measures and data analysis. 16:30:49 16:30:52

Q. Okay. What is the next tobacco-related research that you've done after this "WIC Families Who Smoke" study? 16:30:54 16:31:00 16:31:04

A. Okay. That one is the other one that has 16:31:05

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just been funded, and it is to Dr. Hofstetter that we spoke about earlier, and that is not on here. That's the Korean smoking survey that was funded as of January -- pardon me -- as of July. 16:31:09 16:31:12 16:31:14 16:31:19

Q. And how much is that one again? 16:31:23

A. I'm not sure. I think it's about 5- or $600,000 for three years. 16:31:26 16:31:28

Q. Is that all of the tobacco-related research that you have been engaged in? 16:31:30 16:31:32

A. I believe so. 16:31:34

Q. Now, just eyeballing it, about how much grant funding have you received for your tobacco-related research? 16:31:36 16:31:40 16:31:42

A. Gosh, I'd have to go back and add it up. But it would probably be in the neighborhood of $6 million, $7 million. 16:31:45 16:31:47 16:31:50

Q. Let's see if we can add it up. 16:31:53

MS. FROSTROM: I am going to object that the document speaks for itself. 16:31:55 16:31:56

BY MR. CAFFERTY:

Q. The first one is the "Project Shout," that looks like that's about a million 177. 16:31:57 16:32:01

A. However, that was awarded to Dr. Elder, not to me. 16:32:05 16:32:06

Q. Oh, okay.

A. There was a co-investigator on that. 16:32:08

Q. All right. So let's leave that one out then. And then let's talk -- the first one then 16:32:09 16:32:11

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would be the "Reduction of Passive Smoking in Asthmatic Children," that's 522,000. 16:32:15 16:32:17

A. Uh-huh.

Q. And the next one would be the "Clinician-Initiated Smoking Prevention," that's 2,072,000 -- 16:32:19 16:32:21 16:32:24

A. Uh-huh.

Q. -- correct? 16:32:26

A. Correct. 16:32:26

Q. The next one would be the "Reduction of Passive Smoking in Asthmatic Children," that's 283,000. 16:32:28 16:32:30 16:32:32

A. Uh-huh. That's actually a follow-up to the -- to the passive smoke study. 16:32:36 16:32:39

Q. Okay. So between those two studies, the passive smoke and the follow-up one, we're talking roughly $800,000, it looks like. 16:32:41 16:32:44 16:32:48

A. Uh-huh. 16:32:51

Q. Plus the 2 million 72, so that would be about 2,900,000 -- 16:32:51 16:32:55

A. Correct. 16:32:59

Q. -- approximately. And then we have the "Ninos Sanos," which is 2,600,000. So add that up to the 2.9, that gives us, what, 5.5? 16:32:59 16:33:01 16:33:07

A. About that. 16:33:10

Q. And then we have the "Infant ETS Exposure," that's another million one. 16:33:11 16:33:15

A. Uh-huh.

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Q. So that gives us about, what, 6.6 -- 16:33:18
A. Yeah, about that. 16:33:20
Q. -- million. And then you've got your "WIC Families Who Smoke," that's another 2 million, so that brings us up to 8.6? 16:33:21 16:33:24 16:33:28
A. Uh-huh. 16:33:31
Q. And then the money that you got for the -- or from the Robert Wood Johnson Foundation is about 300,000. So we're talking, round figures, about $9 million? 16:33:32 16:33:37 16:33:40 16:33:45
A. Yes. And I have left one out. If you look on the "State and County," page 5, I was co-investigator with Reimann, about in the middle of the list, for another TRDRP study, which is currently finishing up, looking at the epidemiology of cigar use. That funding, of course, was to a different investigator, however. All of the studies, with the exception of the SHOUT study with Dr. Elder as P.I., have been conducted in the center that I direct, even if I was not the P.I. So I have been involved in both a assistant role, as well as some management -- 16:33:46 16:33:48 16:33:51 16:33:54 16:33:58 16:34:00 16:34:03 16:34:07 16:34:10 16:34:12 16:34:15
Q. Okay. 16:34:18
A. -- in all of them. 16:34:19
Q. And then with the Korean study, we're probably talking the center has about $10 million worth of grant funding? 16:34:21 16:34:23 16:34:27
A. Probably cumulatively it's probably about that. 16:34:30 16:34:32

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Q. Okay. Over about a ten-year period? 16:34:32
A. Uh-huh. 16:34:34
Q. All right. And one of the things I didn't understand when we were talking this morning is about your compensation, that 10 percent. 16:34:34 16:34:35 16:34:38
A. Uh-huh.
Q. What was that, MTE? 16:34:49
A. FTE. 16:34:49
Q. FTE?
A. Full-time equivalent. 16:34:49
Q. When you get that money, the 10 percent FTE, is that in addition to the salary that you get from the university? 16:34:49 16:34:53 16:34:53
A. Yeah. My university has a consulting policy that allows faculty to consult for up to 20 percent of their time, so a day a week equivalent. So, for example, if the Minnesota contract that I have recently negotiated is 10 percent of my time, that's about half of the consulting I'm allowed to do over and above my current salary. 16:34:55 16:34:56 16:34:59 16:35:03 16:35:05 16:35:08 16:35:11
Q. Now, when you do this grant funding -- 16:35:13
A. Uh-huh.
Q. -- do you get paid anything from the grant funds to you personally? 16:35:15 16:35:18
A. In a pass-through fashion. The grant funds will pay for the time that I'm not now paid by the State. The state contract is a 12-month payment sequence, but I'm only paid for a little more than 16:35:20 16:35:23 16:35:28 16:35:31

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seven months a year. So breaks during the academic year and summers are not compensated by the State of California. So that time is allowed to be paid by 16:35:34 16:35:38 16:35:41

other sources of income. That could be any source of income, as -- as would be true of anyone that was part time, in effect. 16:35:42 16:35:45 16:35:47

When I exceed that amount of time, and I have exceeded that amount of time, then if the grant is awarded, and I'm 10 percent on the grant, then I must pay the university back the time that would ordinarily be paid for them, and they release me from teaching or administrative responsibilities. So what that means is I'm paid for the time that is not compensated by the State. And when that is exceeded, I'm then -- I then buy out of the time that would normally be paid by the State. 16:35:51 16:35:54 16:35:57 16:36:01 16:36:04 16:36:08 16:36:11 16:36:14 16:36:17 16:36:21

Q. So you pay the state back money for that portion of the seven months that they paid you for? 16:36:23 16:36:25

A. Correct. Except, actually it's a little worse than that, because the charge -- that charge is not a dollar-for-dollar charge. So if they're paying me a dollar, I may be paying a dollar and a half to buy out of it. It's not exactly that proportion, but it's a higher value to buy out of it than the amount that was actually earmarked for me. So -- 16:36:28 16:36:30 16:36:33 16:36:36 16:36:40 16:36:42 16:36:45

Q. Where does that -- that higher value come from? Is that by contract -- 16:36:47 16:36:49

A. No.

Q. -- or is that by law? 16:36:51

A. That would come from the research grants. You mean where does the formula come from? 16:36:53 16:36:54

Q. Yes. 16:36:57

A. The formula comes from the academic administration of the university. I think their view is that they've invested in their faculty, they want to keep their faculty. If somebody wants to borrow that faculty, then it's going to cost something above and beyond just the straight cost to them. 16:36:57 16:37:00 16:37:02 16:37:06 16:37:08 16:37:10

Q. All right. So, then, would your maximum compensation for the year be 120 percent of your full-time equivalent? 16:37:13 16:37:15 16:37:18

A. About a hundred and -- yeah, at least 120 to 125 percent. Yeah. The way it works is that my full-time equivalent compensation from the academic -- from the academic side, the state funding, is spread out over 12 months. But if you add the additional income that I can -- that I can acquire on my own for the roughly five months not compensated, then that would bring it up to approximately 40 percent increase over the state funding. On top of that I can add 20 percent. 16:37:20 16:37:22 16:37:26 16:37:29 16:37:33 16:37:35 16:37:38 16:37:42 16:37:48 16:37:51

Q. Okay.

A. Does that make sense? 16:37:55

Q. It does, I think. You get paid seven months by the State? 16:37:56 16:37:59

A. Uh-huh. I can add five in. 16:38:00

Q. Plus you get another five months from doing the grant funding? 16:38:01 16:38:03

A. Right. 16:38:04

Q. And then you can get another 20 percent on top of that -- 16:38:04 16:38:07

A. Uh-huh.

Q. -- from the consulting that you do? 16:38:07

A. Correct. 16:38:10

Q. Okay. Let's say over the last five years -- 16:38:10 16:38:12
A. Uh-huh.
Q. -- have you ever had to buy down your seven months from the university? 16:38:15 16:38:19
A. I have been buying down my time from the university for at least the last four or five years. 16:38:21 16:38:24
Q. And how much time do you typically buy down? 16:38:26 16:38:28
A. Normally it's the equivalent of 25 percent a semester. In some semesters it has been as high as 50 percent. And that varies. Last year I think it was 50 percent one semester and 25 for the second semester of that year. And that's been the high end. Previous years it was no more than 25 percent. 16:38:29 16:38:31 16:38:34 16:38:37 16:38:41 16:38:46
Q. When you buydown your contract from the state, does that mean that you're teaching less? 16:38:50 16:38:53
A. Correct. 16:38:56
Q. All right. Is that determined in advance, or is that determined after the fact, how much you're going to buy down? 16:38:56 16:38:59 16:39:01
A. It's normally determined as early and as far in advance as possible. Right now I'm committed to a 25 percent buy down for the coming academic year. However, if a new project came along with short notice, I might increase that, and the university would work with me to do that, which would require identifying a substitute instructor on short notice. 16:39:02 16:39:04 16:39:07 16:39:11 16:39:15 16:39:20 16:39:21 16:39:25
Q. Okay. What areas -- other areas of research are you currently involved in? 16:39:28 16:39:33
A. Many different areas of research, and they cover a wide range by different kinds of categories. Let me start by saying, if you go back to the behavioral epidemiology concept, what we really focus on is behavior, and usually it's an important form of health behavior. So if you categorize it by behavior, we deal with different kinds of either protective behavior or risk behavior. That would include such things as exercise, diet, AIDS risks, which are sexual risks, as well as drug use risks. In some instances we get into both intentional and unintentional injury. Under the intentional injury you would look at things like domestic violence kinds of events. So it's a wide range by behavior. 16:39:40 16:39:42 16:39:44 16:39:47 16:39:50 16:39:54 16:39:58 16:40:00 16:40:03 16:40:09 16:40:13 16:40:16 16:40:20 16:40:24
If we categorize it by disease, we also study behavior within different kinds of disease systems. So we have studied heart disease, diabetes, osteoporosis, arthritis, asthma, cancer, and I may be leaving cystic fibrosis, and the list goes on. Most of the studies that relate to disease, however, remain focused on health behaviors. So this is -- our research is a little bit different from that of some other kind of investigators you may be more familiar with, in that while we care about cystic fibrosis or cancer or AIDS, our primary interest is on understanding the behavior that may be related to that disease process in some way. Usually focused on trying to understand what causes it, and then what we might do to change it. 16:40:27 16:40:30 16:40:35 16:40:39 16:40:48 16:40:54 16:40:55 16:40:59 16:41:02 16:41:04 16:41:07 16:41:11 16:41:13 16:41:20 16:41:22
Q. Over the last five years about how much of 16:41:23

your time, in terms of percentages, has been spent on your tobacco-related research versus the other types of research that you're involved in? 16:41:25 16:41:29 16:41:32

A. Probably about 25 to 30 percent of my research. 16:41:34 16:41:36

Q. Are there any other major contributors to your research time? 16:41:42 16:41:46

A. In terms of money? 16:41:47

Q. In terms of the percentage of your time that you spend. 16:41:48 16:41:50

A. AIDS is a very large area in which we've been investing a lot of time. Not necessarily as much money coming in on it, but a lot of time. We've concentrated on understanding of risk practices in women and risk practices in adolescents that might 16:41:52 16:41:54 16:41:57 16:42:01 16:42:04

lead to AIDS and how we might employ procedures that would prevent them and, therefore, reduce the risk of AIDS. 16:42:07 16:42:11 16:42:14

Q. What areas of science do you consider yourself to be expert in? 16:42:15 16:42:17

A. Well, first of all, I consider myself expert in the methods of science. So -- like a statistician might be an expert in mathematics as used by any number of different researchers for different kinds of science. I'm not a statistician and do not consider myself expert in the statistics. But I do view myself as expert in the research design methodology. And so that cuts across a lot of different areas. And some of the publications in the C.V. that you can look at are concerned with methodological issues, such as how you determine the reliability or validity of measures, including measures of ETS, but not limited to that. 16:42:20 16:42:23 16:42:29 16:42:31 16:42:32 16:42:36 16:42:40 16:42:43 16:42:46 16:42:50 16:42:53 16:42:56 16:43:00

Areas of expertise beyond that would be how to change behavior in general, and specifically health behavior of different kinds. So we spend a good deal of time trying to use what we believe are reliable principles by which to change health-related behavior, and then testing systems of whether those procedures are actually efficacious. That would include with some emphasis on exercise; some emphasis, perhaps a little less emphasis, on diet modification; as I mentioned earlier, risk practices 16:43:02 16:43:05 16:43:08 16:43:12 16:43:15 16:43:20 16:43:23 16:43:29 16:43:33 16:43:37

for AIDS and sexually transmitted disease in pregnancy. And we are moving into areas of injury control. We've done less on that, but that's an area in which we may be doing more in the near future. And then, finally, tobacco control would be a fairly large area of investigation in that overall package. 16:43:41 16:43:50 16:43:57 16:43:59 16:44:03 16:44:05

Q. What do you mean by "injury control"? 16:44:06

A. Well, injury control might -- might be better known in layman language as safety. Where it would be -- it would range, but it would be everything from getting people to wear helmets when they bicycle around, to how you store poisons in a home. It goes way beyond that. You can look at traffic safety, and you can divide it into intentional injury versus unintentional injury. You'll notice we've done some surveys on gun use and locking of guns. We have an evaluation in the field for a thesis study right now that's looking at 16:44:08 16:44:09 16:44:13 16:44:15 16:44:18 16:44:22 16:44:27 16:44:29 16:44:32 16:44:36 16:44:39

trigger locks. So it ranges. 16:44:43
Q. Okay. What do you mean by "tobacco 16:44:44
control"? 16:44:46
A. Tobacco control is efforts to alter the 16:44:49
behavior of using tobacco in some fashion, either by 16:44:51
preventing its use or, for those who are currently 16:44:54
using it, to assist them in stopping. As it applies 16:44:58
to passive smoke exposure, as you've seen from the 16:45:05
studies we've just reviewed, it would be focused on 16:45:05
helping families alter their child's exposure to the 16:45:08

-- usually it's one of the parents smoking. 16:45:10
Q. Are there any other areas of science that 16:45:15
you consider yourself to be expert in beyond methods 16:45:17
of science, changing behavior, injury control and 16:45:20
tobacco control? 16:45:23
A. Exercise science, as I mentioned. I 16:45:25
wouldn't limit it to those areas, because I think 16:45:35
there's a certain generic feature to understanding 16:45:37
health behaviors. So changing the nature of the 16:45:40
specific behavior doesn't necessarily change the 16:45:43
principles involved very much. But those are the 16:45:45
areas in which I've had the greatest experience, I 16:45:48
believe. 16:45:50
Q. Now, methods of science appears to be a 16:45:51
part of your expertise -- 16:45:53
A. Yes. 16:45:55
Q. -- that you will use in this case in 16:45:55
forming your opinions, correct? 16:45:57
A. I actually view that as the primary area of 16:45:58
expertise to be used in this case. 16:46:00
Q. Will you use your changing behavior 16:46:02
expertise in forming your opinions in this case? 16:46:05
A. Not to any great extent, as I understand it 16:46:08
right now. I view this as relationships between 16:46:11
exposure and health outcomes, and there may be 16:46:13
behavior involved in things like measurement concerns 16:46:17
in the course of looking at those associations, but 16:46:21
how one changes behavior does not appear to be 16:46:22

pertinent. 16:46:24
Q. Okay. Would your injury control expertise 16:46:25
serve as the basis for your opinions in this case? 16:46:30
A. Not directly. And if, at all, it would 16:46:33
only be in sensitizing the two, again, measurement 16:46:35
complexities. 16:46:39
Q. Would your exercise science expertise serve 16:46:40
as the basis for your opinions in this case? 16:46:45
A. No. 16:46:46
Q. Would your tobacco control experience serve 16:46:49
as the basis for your expertise? 16:46:55
A. Yes. As we've mentioned earlier, it would, 16:46:55
to the extent that it has taught us a good deal about 16:46:57
how to measure passive smoke exposure. So it comes 16:47:00
back to measurement procedures. 16:47:03
Q. Now, one of the things we talked about this 16:47:05
morning was the work that you've done with 16:47:07
epidemiology studies regarding ETS and health end 16:47:10
points as part of this tobacco control work that you 16:47:15
have done. Referring back to your resume, could you 16:47:17
tell me which of the studies involved -- I guess, 16:47:20
what, was it about eight studies or so that we talked 16:47:24
about -- involved review of epidemiology studies, 16:47:26

human epidemiology studies regarding ETS exposure? 16:47:31
A. All of the tobacco studies that we've 16:47:36
referred to would revolve -- would involve citing 16:47:37
literature at the -- say if we were either writing 16:47:40
the grant, or if we were writing a manuscript about 16:47:43

the studies conducted, that summarizes the degree to 16:47:47
which tobacco is presumed at this stage to be a 16:47:50
health risk, either as a smoker, in the case of 16:47:54
tobacco prevention initiation, or as passive smoke 16:47:57
exposure. So that the distinction I would make there 16:48:01
is that we would tend to summarize those studies in a 16:48:06
very few paragraphs. That's different from a more 16:48:09
detailed and critical review of the same literature. 16:48:14
So, for example, I might believe that the 16:48:16
national EPA review of an issue that is considered a 16:48:21
risk has been done well, and I might cite that as a 16:48:26
standard, saying that one national agency have used 16:48:30
that as a risk practice. Based on that, we would 16:48:32
then go on to review other -- other behavioral 16:48:35
studies that would be looking at how do you change, 16:48:37
say, tobacco initiation in adolescents. 16:48:39
Q. All right. And we talked this morning that 16:48:53
generally the types of health end points that you 16:48:55
have reviewed in performing these tobacco control 16:48:57
studies, we'll call them, have been with respect to 16:49:00
ETS childhood respiratory type studies; is that 16:49:04
right? 16:49:11
A. They've included the asthma, but they've 16:49:11
also included well children. And then, of course, 16:49:14
the one large study that was done on prevention of 16:49:16
smoking in preadolescents and adolescents did not 16:49:19
involve passive smoke exposure. 16:49:23
Q. Did you do a more detailed and critical 16:49:25

type of review for any of those studies as part of 16:49:26
your tobacco control work? You personally, I mean. 16:49:29
A. Yes. The -- if you notice the last few 16:49:33
publications that are listed in here that were in 16:49:36
press, concerns that are published in Tobacco Control 16:49:39
as the journal, that include some reviews of other 16:49:43
passive smoke exposure studies, and it also includes 16:49:46
some reviews of measurements of passive smoke 16:49:49
exposure. The "Trials and Tribulations" article is 16:49:53
that, the latter. 16:49:55
Q. Let's -- let's turn to that, if you could, 16:49:59
just so you could help me understand what it is that 16:49:59
you're referencing here and what type -- what I 16:50:01
really want to understand is what types of reviews 16:50:05
you did of human health epidemiology ETS studies. 16:50:07
A. All right. If you look at reference 125, 16:50:12
which is the last one in this version of the C.V. 16:50:14
Q. Right. 16:50:23
A. This -- this is a review which dealt with 16:50:23
reported measures of environmental tobacco smoke 16:50:23
exposure, and some of the difficulties in designing 16:50:23
and attaining a reliable and valid measure of 16:50:28
exposure. This was primarily concentrated on the 16:50:32
degree to which families can reliably and validly 16:50:35
report exposure in a quantitative fashion. It 16:50:39
doesn't -- pardon me -- it does include reference in 16:50:45
some study of other means by which ETS exposure may 16:50:48
be measured, including air dosimeters, such as the 16:50:53

nicotine filter measure that Kathy Hammonds has used, both active and passive filtering procedures of air sampling. It includes urine cotinine, saliva, and blood cotinine measures, all roughly equivalent in their nature, a form of biomarker that's relatively well respected as a biomarker for tobacco exposure. 16:50:58 16:51:02 16:51:05 16:51:11 16:51:14 16:51:17

And although the literature is somewhat -- at least my understanding of the literature, is somewhat shallower, it also includes respirable particle dosimeters, both active and passive systems of collecting information -- or collecting samples of the particle level from smoke or dust that might have some effect. And all of those have been -- have potential for use in concert with reported measures. 16:51:21 16:51:24 16:51:26 16:51:32 16:51:35 16:51:39 16:51:44 16:51:48

Q. So that -- that review sounds like it's about measurements. 16:51:55 16:51:57

A. Correct. 16:51:58

Q. Have you done, as part of Exhibit 1 -- excuse me -- your Study Number 125, or any of the other studies for that matter, a more detailed and critical review of ETS human health epidemiology studies? 16:51:59 16:52:03 16:52:06 16:52:09 16:52:14

A. No. 16:52:15

Q. As part of the work that you're going to do in this case, do you intend to do a more detailed and critical review of human health ETS studies? 16:52:17 16:52:20 16:52:23

A. I do not intend to do the kind of critical review that has been done by others who are 16:52:27 16:52:29

specialists in the health outcomes that may be pertinent to some of the different areas here. Rather, what I hope to do is review the process by which those studies have been evaluated by others. And in selective study cases I intend to review the methods myself, and reexamine where there may be methodological liabilities. 16:52:31 16:52:33 16:52:35 16:52:38 16:52:42 16:52:47 16:52:52

Q. Is there anything else that you're going to do as part of your more detailed and critical review? Is that the right way to describe it, by the way, a more detailed and critical review? Is that what you mean, or would you define it -- 16:52:55 16:52:57 16:53:01 16:53:04 16:53:05

A. I think that's fine. I think -- let's see if I can explain what I view this. I'm going to look at the EPA report and their process, and -- 16:53:06 16:53:07 16:53:10

Q. Can I interrupt just for a second? I'm sorry. 16:53:15

A. Uh-huh.

Q. You said the "EPA report," did you mean the Cal EPA? 16:53:17 16:53:20

A. Cal EPA report. 16:53:21

Q. Okay.

A. And look at their process by which they reach a conclusion and consensus judgment. I will also look at some of the science that went into that process to, in a sense, sample and confirm some of the judgments that were reached by other kinds of experts than myself. 16:53:21 16:53:24 16:53:27 16:53:30 16:53:33 16:53:35

And then with regard to some of the cardiovascular disease studies, I will do a little bit more than that, to the extent that I'm able to find that literature. I'll look at a few more 16:53:40 16:53:42 16:53:45 16:53:48

studies than I might otherwise. 16:53:54
Q. Okay. How do you intend to do the -- or 16:53:56
how do you intend to identify the science which 16:53:58
you're going to sample regarding the Cal EPA report? 16:54:01
A. My intention is to either go to the most 16:54:05
current literature first, comprehensive reviews, 16:54:08
especially critical reviews. By a critical review, I 16:54:12
mean a review that takes the research methods and 16:54:16
outlines the strengths of the science, and not simply 16:54:20
a summary of five studies that found whatever they 16:54:25
found, but actually reviews them in the context of 16:54:28
their quality. I have an example of that here if 16:54:30
you'd like me to illustrate it. 16:54:35
Q. That would be very helpful, because I'd 16:54:36
like to know what quality criteria you intend to 16:54:39
apply when you do these reviews. 16:54:42
A. Okay. I'll illustrate it first, and then 16:54:43
I'll tell you what the standards are that I'm going 16:54:46
to use. 16:54:48
Q. That would be terrific. 16:54:48
A. As soon as I can find it here. 16:54:50
Q. Can I help you find it? 16:54:52
A. No, it's right here. This is one that you 16:54:52
should have at least the cover on. 16:54:55

Q. Is this one we can make a copy of and label 16:54:59
as a deposition exhibit? 16:55:01
A. I think you have it.
Q. I want you to go home with it. 16:55:04
A. Yeah. I think you have it, but you may. 16:55:06
Absolutely.
Q. All right. Let's do that, and then we'll 16:55:08
make a copy for you before we leave -- 16:55:08
A. Okay. 16:55:10
Q. -- if that's okay. Because I think we only 16:55:09
have the front page. Yes, that's correct. 16:55:12
(Exhibit 566 was marked for
identification.)
BY MR. CAFFERTY:
Q. All right. It's Exhibit 566. 16:55:14
A. All right.
Q. We've marked that. 16:55:16
A. Now, would you like me to explain this 16:55:19
illustration now, and then we -- 16:55:20
Q. Absolutely. 16:55:23
A. Okay.
Q. That would be very helpful. 16:55:23
A. What these -- or this author did was 16:55:25
conducted a meta-analysis of a number of studies that 16:55:32
relate to heart disease and passive smoking in the 16:55:32
workplace. Now, this was one of the studies that I 16:55:35
was reviewing in order to follow Mr. McGuire's 16:55:37
request to take a special look at the heart disease 16:55:40

and vascular disease area. However, my reason for 16:55:43
illustrating it here now has nothing to do with the 16:55:46
disease. It's just about methods. What this -- this 16:55:49
author did was took a number of studies that had been 16:55:53
published in the literature. 16:55:59
Q. Tell you what, let me just take a break 16:56:03
there for a second. I probably have a copy of it 16:56:07
myself. What's the title of that one again? 16:56:08
A. It's the study that was published by Judson 16:56:10

Wells. And it's called "Heart Disease From Passive Smoking in the Workplace." 16:56:12 16:56:14

Q. Maybe not. No, I may not have that one. 16:56:48

A. Okay. Well, I can quickly summarize the main illustrative points, though. What he did was he took the eight or so studies that were considered appropriate for looking at the relationship between passive smoke exposure in the workplace and heart disease, and instead of simply summarizing the odds ratios or relative risk found, or -- 16:56:57 16:57:00 16:57:04 16:57:07 16:57:10 16:57:13 16:57:21

THE REPORTER: I'm sorry. Summarizing the what?

THE WITNESS: Summarizing the odds ratios or relative risk ratios found, he actually ranked the studies in terms of the highest quality science to the weakest quality science. And his ranking was a 1, 2, 3, 4 ranking. Of the -- let's see -- one, two, three, four, five, six, seven or eight studies that he reviewed, he did not rank one of them. He ranked four of them as a 4, which was the poorest quality. He ranked one a 3, one a 2, and one as a 1. 16:57:28 16:57:30 16:57:31 16:57:36 16:57:41 16:57:46 16:57:50 16:57:54

Now, I might or might not agree with his rankings exactly. That wasn't the point of my interest in this study. I wanted to point out that what he has done is what I would consider to be an extremely appropriate and strong design for a meta-analysis or a review paper. What he has done is taken the studies that are relatively weak, those that are intermediate in rigor, and then those that are the best in rigor. And those are not equivalent in what they mean. So he has analyzed the top ranked, I think it was two or three. And when he's done that, he reports a relative risk of about 1.5. When he adds back in the weaker studies, that relative risk drops, and that's -- that's as you would expect, because those weaker studies presumably have more error in them, and the error will cause a weaker association size. They will also bring the significance of the association down, and the confidence center will also drop with that procedure. 16:58:00 16:58:04 16:58:07 16:58:10 16:58:13 16:58:17 16:58:20 16:58:23 16:58:28 16:58:31 16:58:35 16:58:38 16:58:42 16:58:45 16:58:50 16:58:52 16:58:55 16:59:00 16:59:01

So from the logic of science, if you have an extremely poorly designed study with lots of error versus a very high quality science with relatively little error, you have two studies, the validity of the information is presumably greater from the high quality science; and if you average them, you do not necessarily get a good indicator of what they both combine mean. So, arguably, the best science should be averaged, and the weakest science excluded from the averaging in order to draw a conclusion about what it means. 16:59:04 16:59:07 16:59:12 16:59:15 16:59:19 16:59:22 16:59:27 16:59:29 16:59:35 16:59:37 16:59:40

What Wells has done is report the odds ratios based on the best science that he had available and then subsequently show how that odds ratio is reduced by the incremental addition of weaker science. Even with that incremental reduction in odds ratios, he reports a positive odds ratio that remains above 1 in its confidence intervals. 16:59:41 16:59:45 16:59:47 16:59:51 16:59:55 16:59:58 17:00:03

What I will do, when I review the studies that I look at, including the reviews such as this, is I will look for that kind of a logic. And I'm 17:00:07 17:00:11 17:00:13

following classic rules by which one determines causality. The first rule is, have they been able to demonstrate an association. And many of the studies in the ETS literature meet that standard, but not a lot higher. The case control studies may not, for example, do more than say that there's a simple association between some health outcome and exposure in the case versus the control group. But what they may not provide is a quantitative measure. They may not provide dose. There's other characteristics that may be missing. 17:00:17 17:00:21 17:00:26 17:00:31 17:00:35 17:00:38 17:00:41 17:00:44 17:00:48 17:00:50 17:00:53

The next level up would be, if they've shown an association, I would like to know how strong the association is. It has to do with the size of 17:00:55 17:00:58 17:01:02

the association. So an odds ratio of 1.2 would be relatively small. An odds ratio of 2, 3 and 4 would be considered moderate to relatively large. That -- that has implications for the kind of causal agent that may be operating. It also has implications about the kind of error that may be operating in the overall observation of an association. 17:01:06 17:01:10 17:01:14 17:01:18 17:01:27 17:01:29 17:01:32

The next variable, and some might argue the more important next one, is whether the association is consistent. That's measured in a number of different ways. If you see this association in most of the people, so most of the people exposed have an illness and most of the people not exposed don't, that would be viewed as highly consistent. If only a few people who are exposed have the illness, and a few people who are not exposed also have the illness, then that would be evidence of less consistency. That would weaken the logic of causality. I look for that consistency when I'm studying this. 17:01:32 17:01:35 17:01:38 17:01:44 17:01:51 17:01:55 17:01:58 17:02:01 17:02:04 17:02:07 17:02:10 17:02:14

And then, finally, and this is the next-to-the-last measure, is, are all sources of error in confounding accounted for or in some way controlled? And that's a very, very, very severe standard in science, and in that, it wraps up a whole host of procedures. So that includes such things as control for confounding variables in some of these studies have reported the inclusion of control for possible confounding variables. Those studies would 17:02:17 17:02:19 17:02:23 17:02:28 17:02:31 17:02:33 17:02:38 17:02:41 17:02:44

be viewed as stronger in the main than studies that did not. However, most of the studies do not, and maybe cannot, be carried to experimental level where they actually have an experiment where people are randomly assigned, where they are measured prospectively, and where one is treated with exposure and one is not. And ethically we probably can't do that study. But if it could be done, that would be the highest quality science that some -- in some form of experimental validation. 17:02:47 17:02:49 17:02:53 17:02:55 17:02:58 17:03:05 17:03:07 17:03:10 17:03:13 17:03:18

Now, I will look for those kinds of design features when I review individual studies. I will look for those kinds of design issues in someone else's review of a literature. And one of the areas, as I've noted earlier, in which I will pay special attention is the quality of the measurement systems employed. And it is not that I'm looking for a defined high quality measure so much as I'm looking for process by which they've assured me of the level 17:03:22 17:03:25 17:03:28 17:03:31 17:03:35 17:03:38 17:03:40 17:03:45 17:03:48

of the quality of the measures they've used. As I mentioned earlier this morning, that could be, for example, explicit tests of the reliability of a measure and explicit tests of the validity of a measure. And I can give some examples of that, and some of the studies as we go along, if you'd like. 17:03:51 17:03:54 17:03:58 17:04:01 17:04:06 17:04:11

So in answering your question of how will I make my selection, actually the question -- my answer goes to that, as well as to how do I make my judgments once I've read the review or the article. You'll be following those rules of causal logic. 17:04:16 17:04:19 17:04:23 17:04:25 17:04:29

Pardon me, I just remembered I left one of the causals out. 17:04:33 17:04:35

BY MR. CAFFERTY:

Q. I was going to point that out to you. You gave me four, and you said there were five. 17:04:36 17:04:38

A. Well, I left two out. Temporal order, which is one of them. I'm doing this from memory. It's harder without a cheat sheet. So studies that show that the exposure comes first rather than the disease outcome. Now, in the case of ETS exposure and, say, lung cancer -- lung cancer requires a long latency. It usually is a relatively late life event. So the idea that the cancer comes first before exposure is not really plausible. But technically we ought to be sure that the cancer actually followed and didn't precede the, you know, presumed causal agent. And if the study does not include evidence of that, then I would rank that study as less rigorous than one did. 17:04:41 17:04:43 17:04:45 17:04:48 17:04:52 17:04:56 17:05:01 17:05:05 17:05:06 17:05:10 17:05:13 17:05:19 17:05:21 17:05:25

The final variable, and, arguably, this kind of wraps it up in a circular fashion, is theoretical or sometimes referred to as biological plausibility. And the biological plausibility or theoretical plausibility really relates to a different kinds -- another kind of consistency. Not everybody talks about it this way. But, 17:05:26 17:05:31 17:05:34 17:05:37 17:05:42 17:05:45 17:05:49

operationally, what biological plausibility means is that there's a body of literature, and the study that you've done should be -- should be questioned if it is not consistent with the findings of previous high quality studies. So if you were to class studies as meeting a very high standard or a very poor standard, those that meet a very high standard should be held up; and if the new study finds results that are not consistent with it, then you should question those results as being potentially some form of error. 17:05:52 17:05:54 17:05:57 17:06:02 17:06:06 17:06:11 17:06:14 17:06:16 17:06:20 17:06:23

An example of that in the literature, as I've read it so far, would be the -- there are at least one or two studies that have shown a lower than 1.0 relative risk for exposure in children. And my reading of the -- at least one or two of those, the authors do not conclude that exposure to children protects them from cancer. What they conclude is that it is not biologically plausible for this to be a protected event. That doesn't mean it isn't protective. It means new studies have to be done now to verify whether this was some kind of an erroneous observation, or whether it's truly protective. 17:06:30 17:06:32 17:06:36 17:06:39 17:06:45 17:06:55 17:06:55 17:06:55 17:06:58 17:07:01 17:07:04 17:07:07

And that last criterion, which is the biological or theoretical plausibility, also speaks 17:07:12 17:07:16

to the concept of a weight of evidence logic. The weight of the evidence logic is not only looking at say five or six, or eight or ten, or whatever the limited number of studies may be, that have 17:07:19 17:07:22 17:07:27 17:07:30

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specifically examined passive smoke exposure in people, let's say, and a health outcome, but it also would include studies that may have been done in animal models. It would include general pathophysiological studies about pathophysiology, and how that worked, and is there a pathway by which you could see an agent, such as one of the chemical constituents of tobacco, actually having an ill effect. And that entire constellation of research is then to be considered sort of simultaneously in drawing a conclusion as to what the probable causal conclusion should be about a given intervention or agent, whether it be a drug or passive smoke exposure. 17:07:32 17:07:37 17:07:40 17:07:43 17:07:46 17:07:49 17:07:51 17:07:55 17:07:59 17:08:03 17:08:06 17:08:12 17:08:16 17:08:18

So it's really kind of elegant when you step back and think about the science procedure. It's probably the most crucifying process that we've ever invented, because the entire job is to find fault. It makes law look easy. But when you step back and look at it, it doesn't -- if you can pass all of the hurdles with a single study, you have put one small little notch in the -- in the gun belt. You've said, "Okay. We now have one study that seems to have found an association that looks believable." And in the follow-on studies are not generally acceptable, unless they advance the science, which usually means they have to do something better than the previous one, or combination of studies. If they 17:08:19 17:08:22 17:08:24 17:08:28 17:08:34 17:08:38 17:08:42 17:08:46 17:08:51 17:08:52 17:08:55 17:08:58 17:09:01 17:09:03

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do something better, meaning better science, chances are they're going to refute the previous studies, unless those previous studies had found truth. So the standards are incrementally raised all the way through the science process. 17:09:07 17:09:11 17:09:14 17:09:18 17:09:21

An example of that in the drug trial business, Clofibrate is a medication that for many years was on the market, and used routinely by physicians for lowering cholesterol. In studies that had been done to get it through FDA approval showed that it was a very, very reliable and effective means of lowering cholesterol. But like most FDA studies, they were conducted with placebo and randomized, blinded trials, that they were conducted with relatively short-term outcomes. Years after that drug had been on the market it was part of a large study which looked at long-term outcomes, and many drugs were being tested simultaneously and confirmed all of the earlier science that this drug reliably lowers cholesterol. It also reliably killed a slightly larger number of people who took it than the ones who took placebo. And since there were alternative medications that were about as good for lowering cholesterol, the FDA immediately withdrew the licensing for that drug. 17:09:25 17:09:27 17:09:31 17:09:34 17:09:38 17:09:42 17:09:43 17:09:49 17:09:52 17:09:53 17:09:56 17:09:58 17:10:01 17:10:04 17:10:09 17:10:13 17:10:16 17:10:18 17:10:21 17:10:26

That's an example of the advancing science. Here's a drug that had passed this incredible hurdle over years, and was a very effective cholesterol 17:10:27 17:10:29 17:10:32

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medication. But when a longer term study, again with the proper double-blinding and so forth, was done, a subtle but high consequence ill effect was discovered. The high consequence ill effect was that a slightly larger number, and I don't remember the numbers, it was like 2 or 3 percent of the experimental subjects died, whereas only a half a percent or 1 percent of the controls died. That -- that's an illustration of how the science worked when it's working right. 17:10:35 17:10:39 17:10:44 17:10:50 17:10:52 17:10:54 17:10:57 17:11:02 17:11:08 17:11:11

The problem with ETS and the problem with tobacco in general is that it's very difficult, it may be impossible to do controlled trials, controlled experiments, for ethics reasons. If the putative evidence to date suggests that it does predominantly harm and not good, then it would be very difficult -- hard for me to imagine that an institutional review board for the protection of human subjects would ever allow an experiment to be conducted where you actually ask people to be exposed to tobacco, either passively or actively for an extended period of time and compared the health outcomes for people that were asked not to ever be exposed. Feasibility of doing it would be very, very difficult. It would be a hard study design and carry out well. But before you even got to feasibility, its chances are the ethics would preclude it. But that's the standard. 17:11:12 17:11:15 17:11:18 17:11:22 17:11:27 17:11:30 17:11:33 17:11:37 17:11:38 17:11:40 17:11:43 17:11:47 17:11:51 17:11:54 17:11:56 17:12:04 17:12:04

So in the case of epidemiology, we will 17:12:07

back up and use the standards that most closely approximate the classic double-blind clinical trial model, in the absence of being able to actually do that. There is one design that may be feasible -- pardon me -- that may be ethical. It may still have feasibility difficulties. And that would be a reversal experiment. It may be possible to find people who are already exposed, either actively or passively, and then do a controlled trial where some of them are -- are stopped in their exposure if you protect them from exposure and then see if there's a difference in the recovery of ill health, if it is already ongoing, or in the lower rate of longer term health consequences. To my knowledge, that study has not been planned or conducted to date. 17:12:09 17:12:11 17:12:18 17:12:20 17:12:22 17:12:25 17:12:27 17:12:30 17:12:32 17:12:36 17:12:40 17:12:44 17:12:46 17:12:50 17:12:53

Q. Now, we got onto this, we were talking about what it is, the kind of critical -- more detailed and critical review that you were going to be performing, and that was a rather long answer, as you know. What I'd like to know, just briefly, is, what are the quality criteria that you're going to impose when you do your review? 17:12:57 17:12:59 17:13:03 17:13:06 17:13:09 17:13:13 17:13:17

A. Quality criteria will be a look at the studies that have been most current, on the assumption that they're going to have advanced the science or they probably would not have made it into publication. If -- if they are higher quality, meaning they have employed a procedure that 17:13:20 17:13:22 17:13:25 17:13:27 17:13:31 17:13:34

presumably controls some source of error better than the preceding studies. So the first criterion for selection would be currency, with some assumptions being made that that may reflect a more sophisticated research design in some fashion. 17:13:37 17:13:41 17:13:44 17:13:48 17:13:51

Secondly, I will pull reviews of the literature in order to see what others who have done critical reviews have said about the same, or earlier, literature. Usually reviews, due to the lag in publications, are not as current. And then I will go back to either the classic studies that have been cited by some of the literature I do find or to those that may be controversial. So if there is a study that reports, for example, a very large odds ratio, a surprisingly large odds ratio, there may be something peculiar about that study. It's either extraordinarily well done or it has a serious flaw. Either way I would want to look at it. If it reports that there was no finding, but otherwise there was presumably a very strong design operating, then I would want to look at that study very carefully as well to confirm in my own judgment that the design looked as strong as perhaps was reported by the authors or by some other reviewer. 17:13:53 17:13:55 17:13:59 17:14:01 17:14:04 17:14:09 17:14:13 17:14:16 17:14:19 17:14:24 17:14:29 17:14:30 17:14:33 17:14:36 17:14:38 17:14:43 17:14:44 17:14:47 17:14:50

So what I -- what I want to clarify is that my review will be as systematic as I know how. It will be balanced based on design characteristics that I'm looking for, methodological characteristics. But the literature is relatively dense, and some of it is duplicative or repetitive in a way that it's two studies that have done about the same thing and have found about the same thing. I do not expect to review each of those in detail necessarily. 17:14:51 17:14:54 17:14:59 17:15:02

17:15:07 17:15:10 17:15:13 17:15:16 17:15:17

Q. When you do review -- I assume you will review some studies in detail, correct? 17:15:20 17:15:22

A. Yes. 17:15:24

Q. When you do review a study in detail, what are the quality criteria that you will apply in reviewing the study? 17:15:24 17:15:26 17:15:29

A. When I actually examine the study, I'm going to be taking apart their methods. I'm going to be asking -- the broad question is "What might they have done that was wrong?" or "What might they have done that was inadequate to protect the study from sources of error?" Now, incidentally, when I use the word "wrong," that is not a layman's term. That's a technical term for design flaws. It does not mean that the authors were delinquent or mean or bad people or in any way trying to cover up something. It simply means that there was an error that they may not have been able to repair or may not have realized the need to repair. 17:15:32 17:15:35 17:15:39 17:15:42 17:15:44 17:15:46 17:15:50 17:15:52 17:15:56 17:16:00 17:16:05 17:16:07 17:16:12

I can give an example of that. Some of the measures that I've already looked at in a few of the studies have not reported the details of how they've asked the respondents to tell me, or tell us, the level of exposure. They don't give me those details. In some of the studies I've looked at there have been no explicit tests of reliability of their questionnaire measures. That raises a concern for me about the -- the degree to which those measures were reliable. 17:16:14 17:16:16 17:16:18 17:16:24

17:16:27 17:16:30 17:16:32 17:16:35 17:16:39 17:16:41

How does that fit in my overall evaluation? In the computation of an odds ratio, in the computation of the degree to which an odds ratio is statistically significant, error is a part of the 17:16:43 17:16:54 17:16:54 17:16:58

computation. So if you're using a measure which is not reliable, then you're introducing error. That error could be either a lot of error or a little error. But whatever amount of error is going in, it will reduce the size of the association, and it will make that association move towards the nonsignificant end of the continuum. So by not telling me about the reliability of their measures, I'm already alerted to a source of error that would, one, probably lower odds ratios; and, two, lower it towards nonsignificance. 17:16:59 17:17:01 17:17:05 17:17:09 17:17:12 17:17:14 17:17:17 17:17:20 17:17:23 17:17:27 17:17:29

You could have a very large odds ratio that might be due to error as well, although it would still be less likely to be significant. For example, you could have people who, for some reason, falsely reported very, very high -- "false" in the sense meaning inaccurately -- very high exposures that were way above what was true, and controls who might, for 17:17:31 17:17:34 17:17:37 17:17:40 17:17:43 17:17:46 17:17:52

some reason, report very low exposures way below what was true, and you could artificially produce very high odds ratios by that event. Well, if they've shown me the reliability of those measures, then I'm going to assume some of those kinds of reliabilities are lower; or if they've actually shown me the reliability and the reliability is not very good, then I'm going to be -- I will be confirmed in my concern about the measure. 17:17:55 17:17:58 17:18:02 17:18:07 17:18:08 17:18:10 17:18:12 17:18:15 17:18:17

To make that a bit more explicit, in our work where we have compared reported measures, very detailed and relatively comprehensive reported measures of ETS exposure to either nicotine dosimeter measures or cotinine measures, we get varying correlations of approximately .3 to maybe .6, which would be small to moderate associations by most people's judgment, which would be a form of validity checks. And it would say that these are probably valid measures, but they do not predict one another strongly. It's -- it's quite likely some of those measures that have been reported in the literature are not as strong as those that we've used. And I don't know for sure because they aren't reporting those kinds of associations. If they are not, then they may have some serious error built into them. And that would be a concern. 17:18:20 17:18:23 17:18:26 17:18:28 17:18:33 17:18:37 17:18:42 17:18:46 17:18:49 17:18:52 17:18:57 17:19:00 17:19:02 17:19:06 17:19:08 17:19:11 17:19:16

Q. Let's talk about a couple of specific things -- 17:19:18 17:19:19

A. Uh-huh.

Q. -- that you might look at in performing your review of a particular study, an individual study. 17:19:21 17:19:22 17:19:27

A. Okay. 17:19:27

Q. Are you going to look at how confounders were treated? 17:19:27 17:19:29

A. Yes. 17:19:30

Q. And how are you going to do that? 17:19:30

A. Two ways. I'm looking for errors of commission, as well as errors of omission. The latter is the hardest. Most authors are sensitive to certain kinds of potential confounding variables. And they -- if they can -- if it's feasible with their -- with their circumstances and funding level 17:19:33 17:19:35 17:19:39 17:19:44 17:19:47 17:19:50

to build in a procedure that controls for a confounding variable, they usually report that. They do it, and they report it. And we've seen some -- I've seen some studies that have done that. However, it's harder to imagine potential confounding variables that may not have been recognized by the investigators and may not have been addressed adequately. Pardon me. 17:19:55 17:19:56 17:19:58 17:20:00 17:20:04 17:20:08 17:20:11 17:20:13

Again, perhaps because I'm sensitive to measurement, I can think of two that I'm concerned about now. One is that in a case control design where you start with people who have a disease, cancer, let's say, and you find others who do not, 17:20:17 17:20:19 17:20:21 17:20:26 17:20:29

and then you contrast the cases with cancer to those who do not, you then ask them "Can you remember if you've ever been exposed to tobacco?" It's very likely that those people with the disease may be more sensitive and may even be looking for some kind of attribution as to how they acquired this disease. So they may be more likely to report an exposure into those conditions than the controls would be. In that case you would except to have a potentially invalid high odds ratio. So it would -- it would -- it would move you in the direction of reporting an association for ill effects that may not be true. 17:20:32 17:20:35 17:20:38 17:20:42 17:20:47 17:20:50 17:20:52 17:20:55 17:20:58 17:21:02 17:21:05 17:21:07

Q. Is that what's sometimes referred to as recall bias? 17:21:10 17:21:12

A. It's part of the recall bias. Unfortunately, recall bias is a very complex and big monster. Let me carry the analogy a little further. In the case of ETS exposure, there are many different potential sources of exposure. You could be exposed in the community at large. You could be exposed in the workplace. You could be exposed at home. When somebody who has, say, a child at home with asthma, or a family member with lung disease, is asked "How much exposure have you had at home from say a spouse or family member?" there may be a considerable reluctance to admit much exposure. That is, they would under-report exposure because they don't want to blame a family member for their disease. 17:21:13 17:21:16 17:21:19 17:21:25 17:21:28 17:21:32 17:21:34 17:21:38 17:21:40 17:21:47 17:21:52 17:22:01 17:22:01 17:22:04

They might, on the other hand, report more exposure attributable to an employer or to incidental exposure in the community, from a bar or other transportation settings and so forth. So you could end up with recall bias that would artificially lower the odds ratios for specifically residential exposure in order to protect the relationship between the individual with disease and a family member from whom that exposure might be ascribed, or obtained. 17:22:06 17:22:08 17:22:11 17:22:15 17:22:16 17:22:19 17:22:25 17:22:28 17:22:32

That hasn't been mentioned in the studies I've read so far. But I'm very sensitive of that liability, and believe it's probably a confounder in the literature to date. So on the one hand you have certain kinds of confounders that might artificially increase an odds ratio and others that might lower them. 17:22:36 17:22:38 17:22:41 17:22:46 17:22:49 17:22:52 17:22:55

There's another one that is in the literature, and it's been well recognized in the few studies I've read so far, and that has to do with other forms of behavior that may increase or decrease 17:22:56 17:22:57 17:23:00 17:23:03

a risk of an outcome, such as diet and its role in heart disease. Possibly also cancer. 17:23:08 17:23:11

So some of the studies have failed in their association of ETS exposure and, say, cardiovascular outcome, to control for the possibility of other known risk factors for cardiovascular disease. That could include such things as sedentary or physical activity level, saturated fat consumption, and other 17:23:15 17:23:18 17:23:22 17:23:27 17:23:30 17:23:34

qualitative features of the diet, such as antioxidants and other features that are presumed to protect against cancer. 17:23:39 17:23:43 17:23:48

Now, this is where it gets complicated. In studies which have controlled for diet and for activity level, and possibly even obesity or body mass composition, body mass size, they are statistically removing some of the influence that might have been due to those other variables, and the residual influence that's remaining is presumably what's attributable to passive smoke exposure. And normally studies that do that result in lower odds ratios than would have occurred without that adjustment. 17:23:51 17:23:53 17:23:57 17:24:01 17:24:08 17:24:11 17:24:14 17:24:17 17:24:21 17:24:25 17:24:26

The difficulty I see in that logic is that it depends on how you view the causal pathway of ETS, or any agent. If, for example, ETS does cause a change in the vascular system, possibly the cardiac system, then it may make a difference in the oxygen metabolism. If it makes a difference in the oxygen metabolism, then it may make it harder to exercise. If that happens, it may be that you're then less likely to exercise. If you're less likely to exercise, then you're also going to be at higher risk of heart disease, partly due to the consequential decrease in exercise. If you exercise less, then whatever you do eat is likely to result in a higher level of obesity or excess weight. And it may even 17:24:28 17:24:30 17:24:36 17:24:42 17:24:45 17:24:49 17:24:53 17:24:56 17:25:00 17:25:01 17:25:03 17:25:06 17:25:10 17:25:13

inadvertently change the quality of the diet. People who are bored don't exercise a lot, tend to eat a lot of different things. And when you eat a lot of different things, you probably eat more fat. 17:25:16 17:25:20 17:25:25 17:25:28

So it's possible that you can have a complex causal pathway by which a tobacco-related event, such as passive smoking, could influence exercise or directly influence diet, or a combination, which then means that both of those should be in the causal pathway and should not be statistically removed as a confounding variable. So I could argue that when they are reduced -- when the associations are reduced by control of diet or exercise or body mass index, that the resulting odds ratios might be judged as conservative. And they may actually be larger, depending on the causal pathway presumed. 17:25:29 17:25:31 17:25:34 17:25:39 17:25:43 17:25:45 17:25:48 17:25:53 17:25:56 17:25:59 17:26:04 17:26:07 17:26:11

Q. How are you going to make those determinations? 17:26:12 17:26:13

A. I will ask the question of whether they were considered in the studies that were reported. If they have not been considered in the studies, then the new science should take that into consideration. 17:26:14 17:26:16 17:26:18 17:26:21

Q. Which new science? 17:26:23

A. Yet to be done science. 17:26:25

Q. Okay. And that's because additional science is needed in the ETS area? 17:26:26 17:26:27
A. To fully answer those questions. 17:26:29

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Q. Okay. 17:26:31
A. That's right. 17:26:32
Q. Are you also going to look at smoker misclassification when you review these studies? 17:26:33 17:26:35
A. Yes. That's an issue that I think comes up with the child associations that I alluded to earlier. I have not studied all of the literature on this yet, but the little that I've seen so far, I believe most of the investigators are already doing a pretty good job of analyzing the association between children who may be exposed to passive smoke and their subsequent development of, say, lung disease. But in doing that, they've removed people, adults, who have become smokers. 17:26:38 17:26:39 17:26:42 17:26:50 17:26:52 17:26:54 17:26:59 17:27:08 17:27:08 17:27:08
It's quite possible that as a child is exposed to passive smoke, that that exposure contributes to becoming a smoker. Again, if that's true in a causal pathway, then removing people who were smokers makes the subsequent association of children, in absence of later becoming smokers, a very conservative test of the association for children. It's also possible that children who are exposed to passive smoke are more likely to later be exposed to passive smoke as adults, independent of becoming a smoker. And I haven't seen that mentioned in the literature at all. So if I am correct, and it has simply not been addressed yet, that would suggest to me that, while we might argue about which way it 17:27:12 17:27:14 17:27:18 17:27:21 17:27:23 17:27:27 17:27:30 17:27:33 17:27:36 17:27:41 17:27:45 17:27:47 17:27:50 17:27:53

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should be done, it hasn't been considered at all. And that's another potential either confounding variable, or part of a potential causal pathway, where it should not be removed from the analysis. 17:27:55 17:27:58 17:28:01 17:28:05
Q. How will you answer -- how will you answer the question whether or not children exposed to ETS are more likely to be exposed to ETS as adults? 17:28:08 17:28:10 17:28:14
MS. FROSTROM: Incomplete hypothetical. 17:28:18
THE WITNESS: The way I do that is based on other research. Where I know now that children raised in homes with parents who smoke are more likely to smoke themselves, I don't know of any specific research that would tell me that children who are raised and exposed to tobacco smoke are more likely to later be exposed to smoke. But from other information about adaptation to stimuli and adaptation to addictive substances, it's quite likely that if a child, or anybody, were around passive smoke long enough to become comfortable around it, to be adaptive to it, so it is not distressing in a sort of subjective sense, that they might be more easily able to stay in environments where they will remain exposed or continued to be exposed or newly exposed as adults. So it wouldn't be something they would actively avoid. 17:28:21 17:28:23 17:28:25 17:28:28 17:28:30 17:28:33 17:28:36 17:28:40 17:28:44 17:28:48 17:28:51 17:28:54 17:28:57 17:29:00 17:29:02 17:29:06 17:29:09
BY MR. CAFFERTY:
Q. Now you mentioned before, when we went through those six classic rules for causality, that 17:29:11 17:29:13

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those are, in fact, classic rules. Where do those 17:29:17

rules come from? 17:29:20
A. They come from the broad philosophy of 17:29:21
science. One of the investigators, at least in 17:29:24
biology, that's sometimes given credit for the rules 17:29:27
is Koche or Koch's postulates. I noticed in one of 17:29:31
the papers that you provided me, I think it was from 17:29:35
one of the critics of the Cal EPA report, refers to 17:29:37
it I believe as -- I can't do it -- 17:29:42
Q. Did you hear it as part of the Bradford -- 17:29:47
A. Bradford.
Q. -- Hill criteria? 17:29:51
A. Yes, Bradford Hill. And the criteria -- I 17:29:53
just glanced at that. I haven't studied it in 17:29:54
detail. But there are more criteria listed there 17:29:58
than the ones I did. Some of the additional criteria 17:29:59
that are listed are actually subsumed in the five or 17:30:02
six that I listed. So you could break those into 17:30:05
subclasses, in effect. And they were not listed in 17:30:07
quite the same order, in my remembrance of that. But 17:30:10
I have not studied that document closely. I -- I 17:30:12
intend to look at it more thoroughly. 17:30:16
Q. Will you do that before we resume your 17:30:18
deposition? 17:30:20
A. I will try. 17:30:21
Q. Now, because you weren't ready with all of 17:30:22
your opinions today, in fact, with any of your 17:30:25
opinions it sounds like, we're going to have to 17:30:28

continue your deposition at a later date. So 17:30:30
pursuant to our agreement, it's now 5:30, we'll stop 17:30:34
for today. 17:30:38
A. Okay.
Q. And we'll resume again probably in about 17:30:38
three -- three weeks' time, maybe a little bit 17:30:42
longer. We'll work with Ms. Frostrom to come up with 17:30:44
a date for that. 17:30:46
A. Okay.
MR. CAFFERTY: Is that it for today? Does 17:30:48
anybody have anything else? All right. 17:30:49
Thank you very much, Dr. Hovell. 17:30:51
THE VIDEOGRAPHER: This concludes Volume 1 17:30:55
of the videotape deposition of Dr. Melbourne Hovell. 17:30:57
Off the record at 5:30 p.m. 17:31:00
(Whereupon, at 5:35 p.m. the deposition
adjourned.)

* * * * *

I hereby declare under penalty of
perjury that the foregoing deposition is my
deposition under oath; that these are the questions
asked of me and my answers thereto; that I have read
my deposition and have made the necessary

corrections, additions or changes to my answers that I deem necessary.

IN WITNESS THEREOF, I hereby subscribe my name, this _____ day of _____2000.

MELBOURNE HOVELL, Ph.D.